**APPENDIX A**

PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

Nos. 17-3752, 18-1253, 19-1129, 19-1189

COMMONWEALTH OF PENNSYLVANIA;
STATE OF NEW JERSEY

v.

PRESIDENT UNITED STATES OF AMERICA; SECRETARY UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; SECRETARY UNITED STATES DEPARTMENT OF TREASURY; UNITED STATES DEPARTMENT OF TREASURY; SECRETARY UNITED STATES DEPARTMENT OF LABOR; UNITED STATES DEPARTMENT OF LABOR; UNITED STATES OF AMERICA

Little Sisters of the Poor Saints Peter and Paul Home (Intervenor in D.C.),
Appellant in 17-3752, 19-1129

President United States of America, Secretary United States of Department of Health and Human Services, United States Department of Health and Human Services, Secretary United States Department of Treasury, United States Department of Treasury, Secretary United States Department of Labor, United States Department of Labor,
Appellants in 18-1253, 19-1189 (Except President United States of America)

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA
(E.D. Pa. No. 2:17-cv-04540)
District Judge: Hon. Wendy Beetlestone

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Argued May 21, 2019

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Before: McKEE, SHWARTZ, and FUENTES, Circuit Judges.

(Filed July 12, 2019)

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## OPINION OF THE COURT

SHWARTZ, Circuit Judge.

The Women's Health Amendment to the Affordable Care Act ("ACA") mandated that women's health insurance include coverage for preventive health care. Through the Amendment, Congress directed the Health Resources and Services Administration ("HRSA"), a component of the Department of Health and Human Services ("HHS"), to issue guidelines setting forth the preventive health care services that women should be provided. Among the services HRSA identified was contraceptive care. Nowhere in the enabling statute did Congress grant the agency the authority to exempt entities from providing insurance coverage for such services nor did Congress allow federal agencies to issue regulations concerning this coverage without complying with the Administrative Procedure Act.

Notwithstanding Congress's directives, in 2017, HHS and the Departments of Labor and Treasury (collectively, "the Agencies") promulgated regulations that expanded the entities that could invoke an exemption to the requirement that group health insurance plans cover contraceptive services as a form of women's preventive health care. Because the state plaintiffs are likely to succeed in proving that the Agencies did not follow the APA and that the regulations are not authorized under the ACA or required by the Religious Freedom Restoration Act ("RFRA"), we will affirm the District Court's order preliminarily enjoining the rules' enforcement nationwide.

## I

### A

Enacted as a part of the ACA, Pub. L. No. 111-148, 124 Stat. 119 (2010), the Women's Health Amendment mandates that "[a] group health plan[] [1]and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for . . .preventive care and screenings [for women] . . . as provided for in comprehensive guidelines supported by the [HRSA]."[2] 42 U.S.C. § 300gg-13(a), (a)(4). HRSA commissioned an expert panel from the Institute of Medicine to recommend covered services. In 2011, HRSA adopted the Institute's recommendations and issued guidelines defining preventive care to include all "Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity," "as prescribed" by a woman's health care provider. HRSA, *Women's Preventive Services Guidelines*, https://www.hrsa.gov/womens-guidelines/index.html (last visited May 8, 2019). This statutory and regula-

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[1] Pursuant to 42 U.S.C. § 300bb-8(1), the term "group health plan" has the meaning set forth in 26 U.S.C. § 5000(b)(1), which defines a "group health plan" as "a plan (including a self-insured plan) of, or contributed to by, an employer . . . to provide health care (directly or otherwise) to the employees."

[2] Congress expressly exempted two sets of actors from various CA requirements, including the Women's Health Amendment: grandfathered health plans, 42 U.S.C. § 18011, and employers with fewer than 50 employees, 26 U.S.C. § 4980H(c)(2).

tory scheme was deemed the "Contraceptive Mandate." Several regulations and litigation followed.

**1**

The same day that the Guidelines were issued, the Agencies promulgated an interim final rule ("IFR"), followed by a final rule in 2013, to exempt certain religious employers— namely, churches and similar entities—from the Contraceptive Mandate. Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection Affordable Care Act, 77 Fed. Reg. 8,725 (Feb. 15, 2012) (the "Church Exemption"); Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 76 Fed. Reg. 46,621 (Aug. 3, 2011).[3] As the Agencies later explained, the "exemption for churches and houses of worship is consistent with their special status under longstanding tradition in our society and under federal law." Coverage of Certain Preventive Services

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[3] After a notice-and-comment rulemaking process, which included consideration of comments concerning whether coverage may conflict with the religious beliefs of some employers, Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 76 Fed. Reg. 46,621, 46,623 (August 3, 2011), the Agencies defined "religious employer[s]" in the Church Exemption as entities "that [are] organized and operate[] as . . . nonprofit entit[ies] and [are] referred to" as such in the internal revenue code provision applying to "churches, their integrated auxiliaries, and conventions or associations of churches, as well as to the exclusively religious activities of any religious order," Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. 39,870, 39,871, 39,889 (July 2, 2013); *see* 45 C.F.R. § 147.132.

Under the Affordable Care Act, 80 Fed. Reg. 41,318, 41,325 (July 14, 2015).

The 2013 final rule also separately provided that a nonprofit religious employer who "(1) [o]pposes providing coverage for some or all of the contraceptive services required to be covered . . . on account of religious objections; (2) is organized and operates as a nonprofit entity; (3) holds itself out as a religious organization; and (4) self-certifies that it satisfies the first three criteria," 78 Fed. Reg. at 39,874, is entitled to an accommodation to avoid "contracting, arranging, paying, or referring for contraceptive coverage," *id.* at 39,875. This accommodation process (the "Accommodation") permits an employer to send a self-certification form to its insurance issuer, which then excludes contraceptive coverage, either in full or in part, from the group health plan and in turn "provide[s] payments for contraceptive services for plan participants and beneficiaries, separate from the group health plan, without the imposition of cost sharing, premium, fee, or other charge on plan participants or beneficiaries or on the eligible organization or its plan." *Id.* at 39,876. A third party administrator ("TPA") may also be used as a claims or plan administrator "solely for the purpose of providing payments for contraceptive services for participants and beneficiaries in a self-insured plan of an eligible organization at no cost to plan participants or beneficiaries or to the eligible organization." *Id.* at 39,879. By invoking the Accommodation, the employer was no longer responsible for providing coverage for contraceptive care.

Various legal challenges followed. First, in *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682 (2014), the Supreme Court held that the Accommodation must be extended to closely-held for-profit corporations with sincere religious objections to the provision of contraceptive coverage so that their religious beliefs were not substantially burdened under RFRA, 42 U.S.C. § 2000bb-1. *Id.* at 724-26. The Court observed that use of the Accommodation process was a less restrictive means to ensure access to cost-free contraceptives. *Id.* at 730-31. Days later, in *Wheaton College v. Burwell,* 573 U.S. 958 (2014), the Court concluded that Wheaton College, who also lodged a religious objection to providing insurance for services covered by the Contraceptive Mandate, did not have to use the Accommodation self-certification form, known as the ESBA Form 700, but could instead rely on its notification to HHS to satisfy the Accommodation's prerequisites. *Id.* at 959.

To ensure compliance with these rulings, the Agencies promulgated another IFR and final rule.[4] Coverage of Certain Preventive Services Under the Affordable Care Act, 80 Fed. Reg. 41,318 (July 14, 2015). The rule "extend[ed] the [A]ccommodation to a for-profit entity that is not publicly traded, is majority-owned by a relatively small number of individuals, and objects to providing contraceptive coverage based on its owners' religious beliefs." *Id.* at 41,324. The

[4] The final rule implementing *Hobby Lobby* was preceded by notice of proposed rulemaking. Coverage of Certain Preventive Services Under the Affordable Care Act, 79 Fed. Reg. 51,118 (Aug. 27, 2014).

rule also "allow[ed] eligible organizations to choose between using [the] ESBA Form 700 or the alternative process [of notifying HHS in writing of a religious objection to covering contraceptive services] consistent with the *Wheaton* interim order." *Id.* at 41,323.

In *Zubik v. Burwell*, 136 S. Ct. 1557 (2016) (per curiam), the Supreme Court addressed the petitioners' assertions that "submitting [the Accommodation] notice substantially burden[ed] the exercise of their religion, in violation of [RFRA]." *Id.* at 1559. The Court did not reach the merits of this claim but 7parties "an opportunity to arrive at an approach going forward that accommodates petitioners' religious exercise while at the same time ensuring that women covered by petitioners' health plans receive full . . . contraceptive coverage." *Id.* at 1560 (internal quotation marks and citation omitted).

In response to the Court's direction in Zubik, the Agencies solicited comments regarding the current procedure and possible alternatives to the Accommodation. Coverage for Contraceptive Services, 81 Fed. Reg. 47,741 (July 22, 2016). The Agencies reviewed the comments and found that "no feasible approach has been identified at this time that would resolve the concerns of religious objectors while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage." Dep't of Labor, *FAQs About Affordable Care Act Implementation Part 36*, at 4 (Jan. 9, 2017), Available at https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf. As a result, the Accommodation remained unchanged.

**3**

In May 2017, President Donald Trump issued an executive order directing the Agencies to "consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive-care mandate promulgated under [42 U.S.C. § 300gg-13(a)(4)]." Exec. Order No. 13,798 § 3, 82 Fed. Reg. 21,675 (May 9, 2017). In response, and without issuing a notice of proposed rulemaking or soliciting public comment, the Agencies issued two new IFRs: the Religious IFR and the Moral IFR. These IFRs expanded the existing exemption and Accommodation framework, made the Accommodation process voluntary, and offered similar protections to organizations with moral objections to contraceptives. *See* Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,792 (Oct. 13, 2017); Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,838 (Oct. 13, 2017). This litigation followed.

**B**

**1**

The Commonwealth of Pennsylvania filed suit against various governmental entities[5] and sought to enjoin the enforcement of the IFRs. Little Sisters of the Poor Saints Peter and Paul Home ("Little Sis-

[5] These entities include the President, the Agencies and their Secretaries, and the United States of America (collectively, "the Government").

ters") intervened.[6] The District Court granted Pennsylvania's request to preliminarily enjoin the IFRs. *See generally Pennsylvania v. Trump*, 281 F. Supp. 3d 553 (E.D. Pa. 2017). The Court held that Pennsylvania was likely to succeed on its procedural and substantive challenges under the APA. *Id.* at 576, 581. The Government appealed, and the District Court granted a stay pending appeal.

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[6] Little Sisters, a religious nonprofit operating a home in Pittsburgh, moved to intervene, the District Court denied its motion, and our Court reversed, concluding, at that time, intervention was appropriate because the litigation posed a threat to Little Sisters' interest in an exemption, and that its interests are not adequately represented by the Government. *See generally Pennsylvania v. President of the United States of Am.*, 888 F.3d 52 (3d Cir. 2018). Since then, however, the United States District Court for the District of Colorado permanently enjoined enforcement of the Contraceptive Mandate for benefit plans in which Little Sisters participates. *Pennsylvania v. Trump*, 351 F. Supp. 3d 791, 829 n.27 (E.D. Pa. 2019) ("Defendant-Intervenor has secured a permanent injunction, preventing enforcement of the Contraceptive Mandate against it."); *Little Sisters of the Poor v. Azar*, No. 1:13-cv-02611, Dkt. No. 82 at 2-3 (D. Colo. May 29, 2018); Accordingly, Little Sisters is no longer aggrieved by the District Court's ruling, its need for relief is moot, and thus they lack appellate standing. *See Ass'n of Banks in Ins. v. Duryee*, 270 F.3d 397, 403 (6th Cir. 2001) ("[T]he intervenor-defendants face the threat of economic injury should the Ohio statutory provisions not be enforced. Such threatened injury is sufficient to confer appellate standing on the intervenor-defendants and allows them to challenge the merits of the district court's decision."); *cf. In re Grand Jury*, 111 F.3d 1066, 1071 (3d Cir. 1997) ("Since both intervenors remain aggrieved after the district court's disposition, the constitutional requirements for standing to appeal as well as standing to sue are satisfied.").

While the appeal of the order preliminarily enjoining the IFRs was pending, the Agencies promulgated two Final Rules, which are virtually identical to the Religious and Moral IFRs. *See* Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,536 (Nov. 15, 2018); 45 C.F.R. § 147.132 ("Religious Rule" or "Religious Exemption"); Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,592 (Nov. 15, 2018); 45 C.F.R. § 147.133 ("Moral Rule" or "Moral Exemption") (collectively, "the Rules" or "the Exemptions"). Like the Religious IFR, the Final Rule creating the Religious Exemption expanded the categories of employers who are permitted to invoke the exemption from the Contraceptive Mandate to include all nonprofit, for-profit, and publicly-held companies. The Religious Exemption also made participation in the Accommodation process completely voluntarily, relieving employers from the need to "file notices or certifications of their exemption."[7] 83 Fed. Reg. at 57,558; *see also id.* at 57,537, 57,562. The Final Rule creating the Moral Exemption offered the same exemption and voluntary accommodation process to nonprofit organizations and non-publicly traded organizations "with sincerely held moral convictions

[7] The Agencies assert that under ERISA, employees will at least receive notice that their plans no longer cover certain contraceptives because, "with respect to plans subject to ERISA, a plan document must include a comprehensive summary of the benefits covered by the plan," which will "serve to help provide notice to participants and beneficiaries" of what services are covered. 83 Fed. Reg. at 57,558. Even if this is true, this would apply only to certain employers.

opposed to coverage of some or all contraceptive or sterilization methods." *Id.* at 57,593.

At Pennsylvania's request, the District Court lifted the stay, and Pennsylvania filed an amended complaint, joined New Jersey as a plaintiff,[8] added challenges to the Final Rules and moved to enjoin them.[9]

The District Court held hearings and received evidence regarding the Rules. Specifically, the States submitted evidence from health care professionals and state insurance regulators about the Rules' impact. The evidence addressed the relationship between costs and contraceptive use and the impact the Rules would have on state-funded healthcare services.

Cost is a significant barrier to contraceptive use and access. The most effective forms of contraceptives are the most expensive. After the ACA removed cost barriers, women switched to the more effective and expensive methods of contraception.[10] Because the

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[8] Pennsylvania and New Jersey are referred to herein collectively as the "the States."

[9] The States' amended complaint for declaratory and injunctive relief pleads five counts: (I) violation of Equal Protection of the laws under the Fifth Amendment; (II) violation of Title VII of the Civil Rights Act and the Pregnancy Discrimination Act; (III) violation of the procedural requirements of the APA; (IV) violation of the substantive requirements of the APA; and (V) violation of the Establishment Clause of the First Amendment.

[10] Before the ACA, women spent between 30 and 40% of their total out-of-pocket health costs on contraceptives, and 55% of women experienced a time where they could not afford contraceptives. Amicus Curiae Women's Law Ctr. Br. at 15-17; *id.* at 17 (describing that the ACA dropped out-of-pocket contraceptive expenditures by 70%).

Rules allow employers to opt out of providing coverage for contraceptive services, some women may no longer have insurance to help offset the cost for these and other contraceptives.

Pennsylvania and New Jersey have state-funded programs that provide family planning and contraceptive services for eligible individuals. For example, Pennsylvania

Medicaid and New Jersey's FamilyCare[11] cover all health care for childless adults, pregnant women, and parents with incomes up to 138% and up to 215% of the federal poverty level, respectively. Pennsylvania's Family Planning Services Program also covers all family planning-related services, including contraceptives, for individuals with incomes up to 215% of the federal poverty level even if they have private insurance, and New Jersey's Plan First program offers the same for individuals with incomes up to 205% of the federal poverty level.

Women who lack contraceptive coverage and who meet certain income levels may also turn to Title X family planning clinics which "provide access to contraceptive services, supplies, and information to all who want and need them" with priority to low-income persons. Office of Population Affairs, *Funding History*, HHS, https://www.hhs.gov/opa/title-x-family-planning/about-title-x-grants/funding-history/index.html (last visited May 12, 2019). State and federal governments fund Title X clinics, but recently, federal funding has decreased.

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[11] NJ FamilyCare is New Jersey's state and federally-funded Medicaid.

The States expect that when women lose contraceptive insurance coverage from their employers, they will seek out these state-funded programs and services. The States further assert that women who do not seek or qualify for state-funded contraceptives may have unintended pregnancies. Public funds are used to cover the costs of many unintended pregnancies.[12] Accordingly, the States expect to spend more money due to the Rules.

In addition to this evidence, the Agencies presented spread sheets that listed the organizations and companies that were previously involved in ACA Contraceptive Mandate litigation. The Agencies offered this evidence to demonstrate the likely universe of employers whom they contend may seek to invoke the Rules and opt out of covering contraceptive care.

**3**

The day the Final Rules were set to go into effect, January 14, 2019, the District Court issued a nationwide injunction enjoining their enforcement. *Pennsylvania v. Trump*, 351 F. Supp. 3d 791 (E.D. Pa. 2019). The Court found that the States had standing to challenge the Final Rules and established a likelihood of success on the merits of their APA claims. First, the Court held that the States are likely to succeed on their procedural APA claims because the Agencies failed to comply with the notice-and-comment requirement and this defect tainted the Final Rules. *Id.* at 813. Second, the Court held that the

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[12] Nationally, a publicly-funded birth in 2010 cost $12,770, and that year, New Jersey spent an estimated $186.1 million on unintended pregnancies and Pennsylvania an estimated $248.2 million.

States were likely to succeed on their substantive APA challenges because neither the ACA nor RFRA authorized the Agencies to create exemptions. Specifically, the unambiguous language of the ACA's Women's Health Amendment only authorized the Agencies to decide what services would be covered, not who provides them, *id.* at 821, and RFRA did not require or authorize such broad exemptions, particularly given RFRA's remedial function that places the responsibility for adjudicating religious burdens on the courts, not the Agencies, *id.* at 822-23. The Court concluded that the balance of equities and public interest favored an injunction, *id.* at 829-30, and that a nationwide injunction was appropriate to ensure complete relief for the States, *id.* at 834-35. The Government appeals.

## II[13]

We first address whether the States have standing.[14] Article III limits the scope of federal judicial review to "cases" or "controversies." U.S. Const. art. III § 2. A fundamental safeguard of this limitation is the doctrine of standing. *Spokeo, Inc. v. Robins,* 136 S. Ct. 1540, 1547 (2016). Put simply, only parties with standing "can invoke the jurisdiction of the federal courts." *Constitution Party of Pa. v. Aichele*, 757 F.3d 347, 357 (3d Cir. 2014). To have standing to sue,

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[13] The District Court had jurisdiction under 28 U.S.C. § 1331. We have jurisdiction under 28 U.S.C. § 1292(a)(1).

[14] "We review the legal conclusions related to standing *de novo*, but review for clear error the factual elements underlying the District Court's determination of standing." *Edmonson v. Lincoln Nat'l Life Ins. Co.*, 725 F.3d 406, 414 (3d Cir. 2013) (internal quotation marks and citation omitted).

"[t]he plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo*, 136 S. Ct. at 1547 (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)). We will examine each element in turn.

**A**

To establish injury in fact, the alleged injury must be "concrete and particularized" and "actual or imminent, not conjectural or hypothetical." *Id.* at 1548 (quoting *Lujan*, 504 U.S. at 560). An injury is concrete if it "actually exist[s]" and is not abstract. *Id.* "For an injury to be particularized, it must affect the plaintiff in a personal and individualized way." *Id.* (internal quotation marks and citations omitted). Plaintiffs need not "demonstrate that it is literally certain that the harms they identify will come about." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 414 n.5 (2013). Instead, "[a]n allegation of future injury may suffice if . . . there is a substantial risk that the harm will occur." *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014) (internal quotation marks and citation omitted); *see also Clapper*, 568 U.S. at 410 (rejecting lower court's use of an "objectively reasonable likelihood" standard to assess injury).

**1**

The States have established that they will suffer a concrete and particularized injury. The States describe that (1) employers will take advantage of the exemptions and women covered by their plans will lose contraceptive coverage; and (2) financially-eligible women will turn to state-funded services for their contraceptive needs and for the unintended pregnancies that may result from the loss of coverage. As a result, the States will suffer a concrete financial injury from the increased use of state-funded services. *See Cottrell v. Alcon Labs.*, 874 F.3d 154, 163 (3d Cir. 2017) ("Typically, a plaintiff's allegations of financial harm will easily satisfy each of these components, as financial harm is a classic and paradigmatic form[ ] of injury in fact." (alteration in original) (internal quotation marks and citations omitted)). The States will suffer this injury in a particularized manner, as each State's coffers will be depleted by the expenditure of funds to meet the increased demand for state services. Having concluded that the States have identified a concrete and particular injury, we next examine whether the injury at issue is not conjectural and is actual or imminent.

The record shows that the injury the States expect to sustain is not conjectural. First, the Agencies' regulatory impact analysis acknowledges that between 70,500 and 126,400 women nationwide will lose contraceptive coverage as a result of their employers' invocation of the Religious Exemption, 83 Fed. Reg. at 57,578, 57,581, and fifteen women will lose coverage as a result of their employers' use of the Moral Exemption, 83 Fed. Reg. at 57,627. *See California v. Azar* ("*California II*"), 911 F.3d 558, 572 (9th Cir. 2018) (noting that the Agencies' own regulatory impact analysis estimates loss of coverage, and therefore "it is reasonably probable that women in the plaintiff states will lose some or all employer-sponsored contraceptive coverage due to the IFRs"), *cert. denied Little Sisters of the Poor v. California*, No. 18-1192, — S. Ct. —, 2019 WL 1207008 (June 17, 2019) (Mem.).

Second, based on the Agencies' list of entities who challenged the Contraceptive Mandate, eight employers, not including Little Sisters, between New Jersey and Pennsylvania would likely take advantage of the Exemptions. *Massachusetts v. U.S. Dep't of Health & Human Servs.*, 923 F.3d 209, 224 (1st Cir. 2019) (relying on spreadsheet of litigating entities to find "it is highly likely that at least three employers in the Commonwealth with self-insured health plans . . . will use the expanded exemptions"). Accordingly, it is not conjecture to conclude that employers in Pennsylvania and New Jersey will take advantage of the Exemptions and, as a result, women will lose coverage. *Id.* at 224 n.12 (stating that "it is improbable based on the evidence that no women in the [States] would lose contraceptive coverage" (emphasis omitted)).

**2**

The record also supports the District Court's conclusion that the injury is imminent. The States have provided evidence showing that the Exemption will result in the expenditure of state funds because some women who lose coverage will inevitably seek out state-sponsored programs providing contraceptive services; and some women will forego contraceptive use, causing the States to shoulder the costs of unintended pregnancies.

With the ACA, many patients "switch[ed] from a cheaper, less effective [contraceptive] method to a more effective, expensive method that was better for their medical health and personal needs." App. 272. Contraceptives are not only used for pregnancy prevention. They are the "standard first-line of care for a number of hormonal, and other, disorders, including poly-cystic ovarian syndrome, primary ovarian insufficiency/premature ovarian failure, amenorrhea, dysmenorrhea/chronic pelvic pain, and abnormal uterine bleeding." App. 292. A "vast majority" of women use inter-uterine devices ("IUDs")—a treatment religious objectors are particularly focused on, App. 350-83—"for purposes other than birth control." App. 293 (describing 90-95% of patients using IUDs for non-birth control purposes). Contraceptive use "carries long-term health benefits for women[,]" including reducing the risk of ovarian and uterine cancer. App. 294. "Contraception also helps protect the health of those women for whom pregnancy can be hazardous, or even life-threatening." Amici Curiae Health Prof'l Orgs. Br. at 16. Thus, removing cost free contraceptive coverage can have ramifications on women's health beyond birth control and unplanned pregnancies.

Without insurance to defray or eliminate the cost for the more-effective contraceptive methods, women will use "less expensive and less effective methods," App. 245, and both Pennsylvania and New Jersey "anticipate[] that women who lose contraceptive coverage through employer plans—whether the plan of their own employer or that of another family member—may seek contraception from other sources, including state-funded programs."[15] App. 299;

[15] The Agencies "theorize" that some women may be able to pay out of pocket or obtain coverage through a spouse or family member's plan. *Massachusetts*, 923 F.3d at 227. While "[s]uch a hypothetical woman may exist, . the number of women with incomes that make them eligible for state-assisted contraceptive coverage but who still fit in that category would, logically, be very small." *Id.*

App. 317. Thus, the State-funded programs will be tapped to provide coverage for financially eligible women whose employers invoke the Exemptions.

Furthermore, some women who lose contraceptive coverage may either fail to qualify for state services or elect to forego the use of contraceptives altogether. "Women who stop using contraception are more likely to have unplanned pregnancies and to require additional medical attention." App. 312. The costs of such unintended pregnancies are often shouldered by states, costing hundreds of millions of dollars. Therefore, the evidence supports the conclusion that the loss of contraceptive coverage may also result in unintended pregnancies for which the States will bear associated health care costs.

For these reasons, "[t]he expanded exemptions are expected to result in greater financial expenditures" by the States on contraceptive services. App. 318. This anticipated substantial impact on state finances presents an imminent injury. Thus, the District Court properly found that the States showed an imminent injury in fact.

The Government faults the States for failing to identify a specific woman who will be affected by the Final Rules, but the States need not define injury with such a demanding level of particularity to establish standing. *Massachusetts v. EPA*, 549 U.S. 497, 523 n.21 (2007); *see Massachusetts*, 923 F.3d at 225; *California II*, 911 F.3d at 572. The likelihood that employers will invoke the Exemptions and leave women without contraceptive coverage, and that women will turn to the States for coverage, is sufficient to demonstrate imminent injury. This likelihood "has nothing to do with whether petitioners have determined [a] precise" woman who will seek such funding. *Massachusetts*, 549 U.S. at 523 n.21.[16]

**B**

The States' imminent injury is causally connected and fairly traceable to the Exemptions. The States will suffer financial injury when employers in Pennsylvania and New Jersey take advantage of the Exemptions, leaving female employees without contraceptive coverage and prompting financially eligible women to turn to state-funded services. *See Texas v. United States*, 809 F.3d 134, 159 (5th Cir. 2015) ("For Texas to incur injury, DAPA beneficiaries would have to apply for driver's licenses as a consequence of DHS's action, and it is apparent that many would do so."), *aff'd by an equally divided court, United States v. Texas*, 136 S. Ct. 2271 (2016) (Mem.) (per curiam). In other words, the States will not experience an in-

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[16] In the context of an environmental case and a claim that the plaintiff-state Massachusetts lacked standing because it failed to identify land that would be impacted by federal regulators' inaction, the Supreme Court observed that

> the likelihood that Massachusetts' coastline will recede has nothing to do with whether petitioners have determined the precise metes and bounds of their soon-to-be-flooded land. Petitioners maintain that the seas are rising and will continue to rise, and have alleged that such a rise will lead to the loss of Massachusetts' sovereign territory. . . . Our cases require nothing more.

*Massachusetts,* 549 U.S. at 523 n.21. Just as it was unnecessary for Massachusetts to identify specific coastline that would be flooded by the agencies' inaction, it is unnecessary for the States to identify a specific woman who would be impacted by the Government's action where in both instances, the record provided a basis to infer specific imminent injury.

creased demand for services and the resulting financial burden unless the new Exemptions, which create a void in contraceptive coverage, go into effect. *See id.* at 160 ("Far from playing an insignificant role, DAPA would be the primary cause and likely the only one. Without the program, there would be little risk of a dramatic increase in the costs of the driver's-license program."). Thus, there is a link between the Exemptions and the impact on the States' fiscs.

**C**

The District Court also correctly concluded that an injunction would redress the financial injury the States face from the Rules. Enjoining the Final Rules until their legality is adjudicated on the merits will avoid the imminent financial burden the States face if they are not enjoined. *Massachusetts*, 923 F.3d at 228 ("[A]n injunction preventing the application of these exemptions would stop the alleged fiscal injury from occurring, making it not only 'likely,' *Spokeo*, 136 S. Ct. at 1547, but certain that this injury would not occur for as long as the exemptions are enjoined."); *see Massachusetts*, 549 U.S. at 526 ("The risk of catastrophic harm, though remote, is nevertheless real. That risk would be reduced to some extent if petitioners received the relief they seek.").

For these reasons, the States have standing to bring this suit.[17]

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[17] Based upon of the foregoing discussion, we need not decide whether the States also have standing under the special solicitude or parens patriae doctrines.

## III

Having determined that the States have standing, we now address whether they are entitled to a preliminary injunction. The decision to grant or deny a preliminary injunction is within the sound discretion of the district court.[18] *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24, 33 (2008). To obtain a preliminary injunction, the movants must:

> demonstrate (1) that they are reasonably likely to prevail eventually in the litigation and (2) that they are likely to suffer irreparable injury without relief. If these two threshold showings are made the District Court then considers, to the extent relevant, (3) whether an injunction would harm the [defendants] more than denying relief would harm the plaintiffs and (4) whether granting relief would serve the public interest.

*K.A. ex rel. Ayers v. Pocono Mountain Sch. Dist.*, 710 F.3d 99, 105 (3d Cir. 2013) (alteration in original) (quoting *Tenafly Eruv Ass'n v. Borough of Tenafly*, 309 F.3d 144, 157 (3d Cir. 2002)); *accord* Fed. R. Civ. P. 65. To establish a likelihood of success, "a sufficient degree of success for a strong showing exists if there is 'a reasonable chance, or probability, of winning.'" *In re Revel AC, Inc.*, 802 F.3d 558, 568 (3d Cir.

[18] "We employ a tripartite standard of review for . . . preliminary injunctions. We review the District Court's findings of fact for clear error. Legal conclusions are assessed de novo. The ultimate decision to grant or deny the injunction is reviewed for abuse of discretion." *K.A. ex rel. Ayers v. Pocono Mountain Sch. Dist.*, 710 F.3d 99, 105 (3d Cir. 2013) (omission in original) (internal quotation marks and citations omitted).

2015) (quoting *Singer Mgmt. Consultants, Inc. v. Milgram*, 650 F.3d 223, 229 (3d Cir. 2011) (en banc)).

Here, we must decide whether the District Court correctly concluded that the States have a reasonable probability of showing that the Final Rules violate the APA, and if so, whether the equitable factors warrant a nationwide injunction.

### A[19]

To promulgate binding regulations, agencies engage in what is known as notice-and-comment rulemaking. 5 U.S.C. § 553. This requires an agency to publish notice of the proposed rule in the Federal Register, collect and consider public comments, and issue a concise statement of purpose upon finalizing the new rule. *Id.* § 553(b)-(c). Deviation from these procedures is only permitted where expressly authorized by statute, *id.* § 559, or when the agency has "good cause" to dispense with them, *id.* § 553(b)(3)(B). The Agencies assert that both grounds justify their decision to forego notice-and-comment procedures here. They are mistaken.

#### 1

The Government first argues that provisions within the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") grant the Agencies discretion to proceed by IFR in lieu of notice-and-comment

[19] Quite appropriately, the Agencies do not challenge the States' statutory standing to sue under the APA. 5 U.S.C. § 702; *Massachusetts*, 549 U.S. at 520 (recognizing states' "procedural right to challenge the rejection of its rulemaking petition as arbitrary and capricious" under the EPA).

rulemaking. The provisions upon which the Government relies provide:

> The Secretary, consistent with section 104 of [HIPAA], may promulgate such regulations as may be necessary or appropriate to carry out the provisions of this [subchapter]. The Secretary may promulgate any interim final rules as the Secretary determines are appropriate to carry out this [subchapter].

26 U.S.C. § 9833; 29 U.S.C. § 1191c; 42 U.S.C. § 300gg-92 [hereinafter "Regulation Provision"]. This language does not eliminate the need for notice and comment.

First, the APA only allows a subsequent statute to modify or supersede its procedural requirements "to the extent [the statute] does so expressly." 5 U.S.C. § 559. The Regulation Provision contains no express language supplanting APA procedures, and the sole reference to "interim final rules" does not confer a license to ignore APA requirements. Indeed, in contrast to statutory authorizations to forego APA procedures, the Regulation Provision is "permissive ('The Secretary may promulgate any interim final rules as the Secretary determines are appropriate . . .'), wide-ranging (applying to any regulatory proceeding relating to group health insurance plans), and do[es] not contain any specific deadlines for agency action." *Coal. for Parity, Inc. v. Sebelius*, 709 F. Supp. 2d 10, 18-19 (D.D.C. 2010) (omissions in original and emphasis omitted); *see also California II*, 911 F.3d at 578-80. In short, because the Regulation Provision "neither contain[s] express language exempting agencies from the APA nor provide[s] alternative procedures that could reasonably be understood as departing from the APA," it does not authorize the Agencies to disregard the notice-and-comment requirements. *California II*, 911 F.3d at 579.

Second, the statutory reference within the Regulation Provision sheds light on the scope and purpose of its IFR sentence. As the Court of Appeals for the Ninth Circuit points out, § 104 of HIPAA aims to assure regulatory coordination between the Agencies' Secretaries for matters over which they share responsibility. *See California II*, 911 F.3d at 579-80 (citing Pub. L. No. 104-191, 110 Stat. 1936 (1996) (codified at 42 U.S.C. § 300gg-92)). The first sentence of the Regulation Provision authorizes each Secretary to promulgate regulations "consistent with" the HIPAA section on coordination. The second sentence is identical but for two differences: it discusses IFRs instead of final regulations, and it omits any mention of HIPAA's coordination section. Read in light of the first sentence, the second ensures that each Agency can proceed by IFR where a Secretary "need[s] to regulate within his or her own domain temporarily while sorting out . . . inter-agency conflict." *Id.* at 579. Thus, "we need not give the second sentence the [A]gencies' expansive interpretation in order for the second sentence to retain independent effect." *Id.* at 579-80. In sum, the Regulation Provision does not expressly excuse the Agencies from complying with APA procedures and therefore does not provide a basis for issuing the IFRs without notice and comment.[20]

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[20] Congress knows how to excuse an agency from complying with the APA. For example, one HIPAA provision expressly permits the Agencies to promulgate a rule prior to notice and comment.

The Agencies also lacked good cause for dispensing with notice of and comment to the IFRs. An agency has "good cause" to forego APA procedures where following them would be "impracticable, unnecessary, or contrary to the public interest."[21] 5 U.S.C. § 553(b)(3)(B). "[C]ircumstances justifying reliance on [the good cause] exception are indeed rare and will be accepted only after the court has examine[d] closely proffered rationales justifying the elimination of public procedures." Nat. Res. Def. Council, Inc. v. EPA ("NRDC"), 683 F.2d 752, 764 (3d Cir. 1982) (alterations in original) (internal quotation marks and citation omitted). Thus, we construe the "good cause" ex-

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42 U.S.C. § 1320a-7b note. That provision requires the Secretary of Health and Human Services to publish a rule prescribing penalties for kickbacks by January 1, 1997, then less than four months away. It provides that "[s]uch rule shall be effective and final immediately on an interim basis, but is subject to change and revision after public notice and opportunity for . . . public comment." Unlike the Regulation Provision, § 1320a-7b expressly provides for notice and comment after the promulgation of an IFR. Congress's omission of that procedure from the Regulation Provision demonstrates that it did not provide the Agencies authority to promulgate IFRs without notice and comment.

[21] 5 U.S.C. § 553(b)(3) provides

> [e]xcept when notice or hearing is required by statute, this subsection does not apply—
>
> . . .
>
> (B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

ception to the notice-and-comment requirement narrowly.[22] *Id.*

When they issued the IFRs, the Agencies claimed good cause to waive notice and comment based on (1) the urgent need to alleviate harm to those with religious objections to the current regulations; (2) the need to address "continued uncertainty, inconsistency, and cost" arising from "litigation challenging the previous rules"; and (3) the fact that the Agencies had already collected comments on prior Mandate-related regulations. 82 Fed. Reg. at 47,813-15; *see also* 82 Fed. Reg. at 47,855-59. None of these assertions meet the standard for good cause.

First, the Agencies' desire to address the purported harm to religious objections does not ameliorate the need to follow appropriate procedures. All regulations are directed toward reducing harm in some manner.[23] *See United States v. Reynolds*, 710 F.3d

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[22] Though the review standard for agency assertions of good cause remains an open question in our circuit, *see United States v. Reynolds*, 710 F.3d 498, 509 (3d Cir. 2013), we need not answer that question here. Even applying the most deferential of the potential standards—reviewing the agency's good cause determination to see if it is arbitrary and capricious—the IFRs cannot stand.

[23] As we observed in *Reynolds*,

> [m]ost, if not all, laws passed by Congress requiring agencies to promulgate new rules are designed to eliminate some real or perceived harm. If the mere assertion that such harm will continue while an agency gives notice and receives comments were enough to establish good cause, then notice and comment would always have to give way. An agency will invariably be able to point to

498, 512-13 (3d Cir. 2013). Thus, "[a] need to regulate affected parties does not create the urgency necessary to establish good cause." *Id.* at 511. "As with any other administrative agency conclusion, we require some statement of facts or circumstances that justifies the existence of good cause (e.g., an imminent, externally imposed deadline or the existence of an emergency)." *Id.* at 512. The Agencies fail to cite any facts or impending deadlines sufficient to raise "good cause" here.

Second, the need to address uncertainty is likewise insufficient to establish good cause. Uncertainty precedes every regulation, and to allow uncertainty to excuse compliance with notice-and-comment procedures "would have the effect of writing [those] requirements out of the statute." *Id.* at 510. Furthermore, our precedent forecloses the acceptance of uncertainty as a basis for good cause. *Id.* ("An agency's intention to provide clarity, without more, cannot amount to good cause.").

Third, the Agencies' previous solicitation and collection of comments regarding other rules concerning Contraceptive Mandate cannot substitute for notice and comment here. If the APA permitted agencies to forego notice-and-comment concerning a proposed regulation simply because they already regulated similar matters, then the good cause exception could largely obviate the notice-and-comment requirement. Furthermore, the IFRs did not make a minor change.

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some continuing harm during the notice and comment period antecedent to the promulgation of a rule.

710 F.3d at 512-13.

The IFRs create exemptions from the Contraceptive Mandate with unprecedented scope and make the Accommodation wholly voluntary. Such a dramatic overhaul of the Contraceptive Mandate regulations required notice-and-comment under the APA.

For these reasons, the Agencies did not have good cause to ignore the APA's notice and comment requirement.

**B**

The Government also contends that, even if the IFRs were procedurally deficient, the Agencies' subsequent use of notice-and-comment rulemaking to finalize the Rules cured any procedural defects. Under our precedent, however, "post-promulgation notice and comment procedures cannot cure the failure to provide such procedures prior to the promulgation of the rule at issue." *NRDC*, 683 F.2d at 768; *see Reynolds*, 710 F.3d at 519 ("Any suggestion that the post promulgation comments to the Interim Rule can satisfy [the purposes of notice-and-comment rulemaking] misses the point." (internal citation omitted)); *Sharon Steel Corp. v. EPA*, 597 F.2d 377, 381 (3d Cir. 1979) ("We hold that the period for comments after promulgation cannot substitute for the prior notice and comment required by the APA.").

APA notice-and-comment procedures serve several goals, including "(1) to ensure that agency regulations are tested via exposure to diverse public comment, (2) to ensure fairness to affected parties, and (3) to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review." *Prometheus Radio Project v. FCC*, 652 F.3d

431, 449 (3d Cir. 2011) (quoting *Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin.*, 407 F.3d 1250, 1259 (D.C. Cir. 2005)). The comment process also allows each agency to "maintain[] a flexible and open-minded attitude towards its own rules," *Reynolds*, 710 F.3d at 511 (alteration in original and citation omitted) (quoting *Prometheus Radio*, 652 F.3d at 449); *see also Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1816 (2019) ("Notice and comment . . . affords the agency a chance to avoid errors and make a more informed decision." (internal citation omitted)). To preserve the integrity of this process, "[t]he opportunity for comment must be a meaningful opportunity," *Prometheus Radio*, 652 F.3d at 450 (alteration in original), to have interested parties share their views, and to have the agency consider them with an "open mind," *Reynolds*, 710 F.3d at 517-19.

The notice and comment exercise surrounding the Final Rules does not reflect any real open-mindedness toward the position set forth in the IFRs.[24] First, as the Government admits, the minor changes to the Final Rules do not "alter the fundamental substance of the exemptions set forth in the IFRs." Dkt. 107-1 at 8. Second, the reasons the Agencies supplied for promulgating the Final Rules simply echoed those provided for issuing the IFRs. *See* 83 Fed. Reg. at 57,552, 57,609. These rationales do not show the "flexible and open-minded attitude" the notice-and-comment process requires. *Reynolds*, 710

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[24] We express no opinion on whether the Agencies appropriately responded to comments collected during this process, *see Trump*, 351 F. Supp. 3d at 811-12, as this issue is not before us.

F.3d at 511. Together, the Agencies' justifications for avoiding notice and comment to the IFRs, and the fact that the IFRs and the Final Rules are virtually identical, suggest that the opportunity for comment was not a "meaningful" one in the way the APA requires. *Prometheus Radio*, 652 F.3d at 450.

Lastly, even setting aside the Agencies' lack of open-mindedness, the IFRs also impaired the rulemaking process by altering the Agencies' starting point in considering the Final Rules. In *NRDC*, our Court rejected the EPA's argument that the opportunity for post-promulgation comment remedied the EPA's initial failure to promulgate a rule through notice-and-comment rulemaking:

> [t]o allow the APA procedures in connection with the [new rule] to substitute for APA procedures in connection with [the initial, procedurally defective rule] would allow [the] EPA to substitute post-promulgation notice and comment procedures for pre-promulgation notice and comment procedures at any time by taking an action without complying with the APA, and then establishing a notice and comment procedure on the question of whether that action allow agencies to circumvent [our case law] and the APA. We cannot countenance such a result.

683 F.2d at 768 (citation omitted). This reasoning applies with equal force here. By first promulgating the IFRs that granted the expanded exemptions without notice and comment, the Agencies changed the question presented concerning the Final Rules from whether they should create the exemptions to whether they should depart from them. This starting posi-

tion is impermissible under the APA. *Id.*; *see also Sharon Steel*, 597 F.2d at 381 ("Provision of prior notice and comment allows effective participation in the rulemaking process while the decisionmaker is still receptive to information and argument. After the final rule is issued, the petitioner must come hat-in-hand and run the risk that the decisionmaker is likely to resist change." (citation omitted)).

In sum, because deficits in the promulgation of the IFRs compromised the procedural integrity of the Final Rules, the States have demonstrated a likelihood of success in showing that the Final Rules are procedurally defective, and in turn, violate the APA.

**C**

There are also serious substantive problems with the Final Rules. More specifically, neither of the statutes upon which the Agencies rely, the ACA and RFRA, authorize or require the Final Rules. Thus, they were enacted "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," making them "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A), (C).

**1**

The Agencies argue that their authority under the ACA to issue preventive care guidelines includes the power to promulgate the Exemptions. This assertion is without textual support. The Women's Health Amendment to the ACA, 42U.S.C. § 300gg-13(a)(4), provides:

> A group health plan and a health insurance issuer offering group or individual health insur-

> ance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for— . . .
>
> (3) with respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the [HRSA].
>
> (4) with respect to women, such additional preventive care and screenings not described in paragraph (1)[25] as provided for in comprehensive guidelines supported by the [HRSA] for purposes of this paragraph.

42 U.S.C. § 300gg-13(a). The authority to issue "comprehensive guidelines" concerns the type of services that are to be provided and does not provide authority to undermine Congress's directive concerning who must provide coverage for these services. Section 300gg-13(a) unambiguously dictates that group health plans and health insurance issuers "shall provide" the preventive care services set forth in the HRSA-supported comprehensive guidelines, and "shall" not impose cost sharing. The term "shall" denotes a requirement, *Prometheus Radio Proj. v. FCC*, 824 F.3d 33, 50 (3d Cir. 2016) ("Th[e] repeated use of 'shall' creates 'an obligation impervious to . . . discretion.'" (omission in original) (quoting *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 35 (1998)), and HRSA's authority to issue the guide-

[25] Paragraph (1) refers to "evidence-based items or services that have in effect a rating of 'A' or 'B' in the current recommendations of the United States Preventive Services Task Force." 42 U.S.C. § 300gg-13(a)(1).

lines does not empower it to ignore that requirement. Nothing from § 300gg-13(a) gives HRSA the discretion to wholly exempt actors of its choosing from providing the guidelines services. On the contrary, the mandate articulated in § 300gg-13(a) forecloses such exemptions.[26]

The Agencies' reliance on the language that directed HRSA to create the guidelines concerning women's preventive health care and the use of the phrase "as provided for in" such guidelines does not advance their position. The Agencies contrast § 300gg-13(a)(4)'s use of the phrase "as provided for in" comprehensive guidelines with a neighboring subsection's provision addressing preventive care for infants, children, and adolescents, which is "provided for in the" comprehensive guidelines for those services. *Compare* 42 U.S.C. § 300gg-13(a)(3) (describing

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[26] The Government argues that if the ACA does not grant the authority to issue the Exemptions, then HRSA was equally without authority to issue the Church Exemption and the Accommodation. This argument fails. Though the Church Exemption may seem facially at odds with § 300gg-13(a), Supreme Court precedent dictates a narrow form of exemption for houses of worship. *See* 80 Fed. Reg. at 41,325 (describing the exemption for churches and houses of worship as "consistent with their special status under longstanding tradition in our society and under federal law"); *see, e.g., Hosanna-Tabor Evangelical Lutheran Church & Sch. v. EEOC*, 565 U.S. 171 (2012) (discussing the existence of a ministerial exception precluding application of employment legislation to a religious institution to respect churches' internal autonomy). The Accommodation likewise does not plainly run afoul of the ACA. Instead, it provides a process through which a statutorily identified actor "shall provide" the mandated coverage. In any event, the Agencies' authority to issue the Church Exemption and Accommodation is not before us.

"preventive care and screenings provided for in the comprehensive guidelines"), *with id.* § 300gg-13(a)(4) (describing "preventive care and screenings as provided for in comprehensive guidelines"). They assert that the use of the word "as" in § 300gg-13(a)(4) gives HRSA authority to dictate the preventive services to be provided and who must provide them. This argument overlooks the clear explanation for the different language. When the ACA was passed, the comprehensive guidelines for children's preventive care already existed, but guidelines for women's preventive care were not yet written. Congress used the definite article "the" in § 300gg-13(a)(3) to refer to those existing children's preventive care guidelines. In § 300gg-13(a)(4), Congress addressed the women's preventive care guidelines that were yet to be promulgated by stating "as provided for in comprehensive guidelines."

The Agencies' interpretation of "comprehensive" as authorizing them to issue guidelines that exempt entities from complying with the Mandate likewise fails. Put simply, the discretion the statute grants HRSA to issue comprehensive guidelines concerning services to be provided does not include the power to exempt actors from the statute itself. This is borne out by the fact that the word "comprehensive" is also used to describe the children's preventive care guidelines, and those guidelines do not exempt any statutorily required party from providing services. *See* HHS, *Preventive Care Benefits for Children*, https://www.healthcare.gov/preventive-care- children (last visited May 8, 2019). Congress was obviously aware of the existing children's guidelines when it drafted the Women's Health Amendment, and Congress's use of "comprehensive" to describe both sets of guidelines conveys that it intended them to cover the same type of subject matter, namely health care services for the identified groups. *See F.A.A. v. Cooper*, 566 U.S. 284, 292 (2012) ("[W]hen Congress employs a term of art, it presumably knows and adopts the cluster of ideas that were attached to each borrowed word in the body of learning from which it was taken." (internal quotation marks and citation omitted)).

Other portions of the ACA also show that Congress retained the authority to exempt certain employers from providing contraceptive coverage. In passing the ACA, Congress explicitly exempted grandfathered plans from the Contraceptive Mandate and other ACA requirements. 42 U.S.C. § 18011(a), (e). Congress also considered and rejected a statutory conscience amendment that would have operated similarly to the challenged Exemptions. 158 Cong. Rec. S1162, 1173-74 (2012). Between the substantially analogous exemption Congress rejected, and the one it decided to keep, Congress demonstrated that exempting specific actors from the ACA's mandatory requirements is its job, not the Agencies. *See United States v. Johnson*, 529 U.S. 53, 58 (2000) ("When Congress provides exceptions in a statute," we may infer "that Congress considered the issue of exceptions and, in the end, limited the statute to the ones set forth."). Relatedly, by promulgating the Moral Exemption, which sought to do what Congress refused to do with the conscience amendment, the Agencies contravened Congress's intent. *See Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 147 (2000) (considering Congress's prior refusal to pass laws as material to whether an agency's interpretation of its statute is entitled to deference).

Because § 300gg-13(a) does not authorize the Agencies to exempt plans from providing the required coverage, the Agencies' authority under the ACA to enact the Final Rules is without merit.

**2**[27]

The Agencies' effort to cast RFRA as requiring the Religious Exemption is also incorrect. Even assuming that RFRA provides statutory authority for the Agencies to issue regulations to address religious burdens the Contraceptive Mandate may impose on certain individuals, RFRA does not require the enactment of the Religious Exemption to address this burden.

RFRA provides that the federal government "[s]hall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability," 42 U.S.C. § 2000bb-1(a), unless "that application of the burden to the person—(1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest," *id.* § 2000bb-1(b). "[A] person whose religious exercise has been burdened in violation of this section" may seek relief in a judicial proceeding. *Id.* § 2000bb-1(c). Thus, RFRA authorizes a cause of action for government actions that impose a substantial burden on a person's sincerely-held religious beliefs, and provides a judicial remedy via individualized adjudication. *See* 42 U.S.C. § 2000bb-3(a); *City of Boerne v. Flores*, 521 U.S. 507, 529 (1997) ("[RFRA] prevents and remedies laws which are enacted with the unconstitutional ob-

[27] No party argues that RFRA authorizes or requires the Moral Exemption.

ject of targeting religious beliefs and practices."). Because Congress has deemed the courts the adjudicator of private rights of actions under RFRA, *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 434 (2006) (holding RFRA "plainly contemplates that courts would . . . consider whether exceptions are required under the test set forth by Congress" (emphasis omitted)), we owe the Agencies no deference when reviewing determinations based upon RFRA, *see Adams Fruit Co., Inc. v. Barrett*, 494 U.S. 638, 649 (1990) (declining to defer to an agency's statutory interpretation where Congress "expressly established the Judiciary and not the [agency] as the adjudicator of private rights of action arising under the statute").

A prima facie RFRA case requires a plaintiff to prove that the government imposed a substantial burden on religious exercise. *Mack v. Warden Loretto FCI*, 839 F.3d 286, 304 (3d Cir. 2016). A substantial burden exists if

> (1) a follower is forced to choose between following the precepts of his religion and forfeiting benefits otherwise generally available to other [persons] versus abandoning one of the precepts of his religion in order to receive a benefit; or (2) the government puts substantial pressure on an adherent to substantially modify his behavior and to violate his beliefs.[28]

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[28] Although we "defer to the reasonableness" of an objector's religious beliefs, "this does not bar our objective evaluation of the nature of the claimed burden and the substantiality of that burden on [the objector's] religious exercise." *Real Alternatives, Inc.*

*Real Alternatives, Inc. v. Sec'y Dep't of Health & Human Servs.*, 867 F.3d 338, 371 (3d Cir. 2017) (alteration in original) (internal quotation marks and citation omitted). The Supreme Court has directed that, when considering a requested accommodation to address the burden, "courts must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries."*Cutter v. Wilkinson*, 544 U.S. 709, 720 (2005) (referring to third parties who may face collateral consequences from accommodating an observer's burden).[29] The Accommodation fulfills this directive as it provides a means for an observer to adhere to religious precepts and simultaneously allows women to receive statutorily-mandated health care coverage.

RFRA does not require the broad exemption embodied in the Final Rule nor to make voluntary a notice of the employer's decision not to provide such coverage to avoid burdening those beliefs. As our Court has explained,

> the self-certification form does not trigger or facilitate the provision of contraceptive coverage because coverage is mandated to be otherwise provided by federal law. Federal law, rather than any involvement by the [employers] in

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*v. Sec'y Dep't of Health & Human Servs.*, 867 F.3d 338, 356 (3d Cir. 2017) (emphasis omitted) (citation omitted).

[29] Although *Cutter v. Wilkinson*, 544 U.S. 709 (2005), dealt with an application of the Religious Land Use and Institutionalized Persons Act ("RLUIPA"), we have said that RLUIPA and RFRA "are analogous for the purpose of the substantial burden test," and we may therefore may apply RLUIPA law. *Mack*, 839 F.3d at 304 n.103; *see Holt v. Hobbs*, 135 S. Ct. 853, 860 (2015).

> filling out or submitting the self-certification form, creates the obligation of the insurance issuers and third-party administrators to provide coverage for contraceptive services. . . .
>
> [And] the submission of the self-certification form does not make the [employers] "complicit" in the provision of contraceptive coverage.

*Geneva Coll. v. Sec'y of U.S. Dep't of Health & Human Servs.*, 778 F.3d 422, 437-38 (3d Cir. 2015) (emphasis omitted), *vacated and remanded sub nom. Zubik*, 136 S. Ct. 1557.[30]

The religious objectors who oppose the Accommodation mechanism disapprove of "what follows from" filing the self-certification form, but under Free Exercise jurisprudence, we examine the conduct of the objector, not third parties. *Id.* at 439-40. Here, through the Accommodation process, "the actual provision of contraceptive coverage is by a third party," so any possible burden from the notification procedure is not substantial. *Id.* at 442. For these reasons, RFRA does not require that the Agencies permit religious objectors to decline to provide contraceptive coverage without notifying their insurance issuer, TPA, HHS, or the employees.

Contrary to the Agencies' assertions in the Rule, the Supreme Court has not held that the Accommodation imposes substantial burdens on religious

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[30] While *Zubik* vacated our opinion in *Geneva College*, it did not reach the merits of the Accommodation nor did it "attack our reasoning." *Real Alternatives*, 867 F.3d at 356 n.18. After *Zubik*, we repeated that the Accommodation does "not impose a substantial burden." *Id.*

rights. *Hobby Lobby* ruled that closely-held corporations are entitled to take advantage of the Accommodation process rather than facing fines for non-compliance with the contraceptive mandate, observing that the Accommodation was a less restrictive alternative to forcing objectors to choose between adhering to the mandate or violating their sincerely-held beliefs. 573 U.S. at 730-31. While the Court "did not decide" whether the Accommodation "complies with RFRA," it found that "[a]t a minimum . . . it does not impinge on that plaintiffs' religious belief that providing insurance coverage for [certain contraceptives] violates their religion, and it serves HHS's stated interests equally well." *Id.* at 731; *see also Zubik*, 136 S. Ct. at 1561 (Sotomayor, J., concurring) ("The opinion does not . . . endorse the petitioners' position that the existing regulations substantially burden their religious exercise or that contraceptive coverage must be provided through a separate policy, with a separate enrollment process." (internal quotation marks and citations omitted)); *Wheaton*, 573 U.S. at 960 (noting that *Hobby Lobby* "expressly rel[ied] on the availability of the religious-nonprofit accommodation" to reach its holding).

Furthermore, the Religious Exemption and the new optional Accommodation would impose an undue burden on nonbeneficiaries—the female employees who will lose coverage for contraceptive care. The Agencies downplayed this burden on women, contradicting Congress's mandate that women be provided contraceptive coverage. "No tradition, and no prior decision under RFRA, allows a religion-based exemption when the [A]ccommodation would be harmful to others—here, the very persons the contraceptive coverage requirement was designed to protect." *Hobby*

*Lobby*, 573 U.S. at 764 (Ginsburg, J., dissenting). As the Agencies recognize, the record shows that thousands of women may lose contraceptive coverage if the Rule is enforced and frustrate their right to obtain contraceptives. *Id.* at 727 (citation omitted); 42 U.S.C. § 300gg-13(a)(4) (directing the enactment of the Women's Preventive Services Guidelines, which include contraceptives).

In short, the status quo prior to the new Rule, with the Accommodation, did not infringe on the religious exercise of covered employers, nor is there a basis to conclude the Accommodation process infringes on the religious exercise of any employer. For these reasons, RFRA does not demand the Religious Exemption.

**D**

Because the States demonstrated a likelihood of success on the merits as to their APA claim, we next turn to the remaining equitable factors. To obtain a preliminary injunction, a plaintiff must "demonstrate that irreparable injury is likely in the absence of an injunction." *Winter*, 555 U.S. at 22 (emphasis omitted). Because the States cannot collect money damages under the APA,[31] 5 U.S.C. § 702 (enabling claimants to obtain "relief other than money damages"); *see also California_II*, 911 F.3d at 581, the States will suffer irreparable harm if the Rules are enforced. The States will face unredressable financial consequences from subsidizing contraceptive services,

[31] Monetary injuries ordinarily do not constitute irreparable harm because they are compensable. *See Instant Air Freight Co. v. C.F. Air Freight, Inc.*, 882 F.2d 797, 801 (3d Cir. 1989).

providing funds for medical care associated with unintended pregnancies, and absorbing medical expenses that arise from decreased use of contraceptive medications for other health conditions. Therefore, the District Court did not abuse its discretion in holding that the States demonstrated a likelihood of irreparable harm.

Furthermore, because the current Accommodation does not substantially burden employers' religious exercise and the Exemption is not necessary to protect a legally-cognizable interest, the States' financial injury outweighs any purported injury to religious exercise. Moreover, the public interest favors minimizing harm to third-parties by ensuring that women who may lose ACA guaranteed contraceptive coverage are able to maintain access to the preventive care to which they are entitled under the ACA and HRSA's comprehensive guidelines while final adjudication of the Rules is pending. Therefore, the District Court did not abuse its discretion in concluding that the balance of the equities and the public interest both favor issuing an injunction.

**E**

Having determined that a preliminary injunction is warranted, the final question we address is whether the District Court abused its discretion by enjoining the Final Rules nationwide. "Crafting a preliminary injunction is an exercise of discretion and judgment, often dependent as much on the equities of a given case as the substance of the legal issues it presents." *Trump v. Int'l Refugee Assistance Project*, 137 S. Ct. 2080, 2087 (2017) (per curiam). While courts are vested with the power to issue equitable relief with a nationwide reach, *see Texas*, 809 F.3d at 188 (quoting

U.S. Const. art. III, § 1), they must ensure that "injunctive relief [is] no more burdensome to the defendant than necessary to provide complete relief to plaintiffs," *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharm. Co.*, 290 F.3d 578, 598 (3d Cir. 2002) (internal quotation marks and citation omitted). We must also bear in mind that the purpose of injunctions is "not to conclusively determine the rights of the parties, but to balance the equities as the litigation moves forward." *Trump*, 137 S. Ct. at 2087 (internal citation omitted).

Mindful of these considerations, the District Court did not abuse its discretion in concluding that a nationwide injunction is necessary to afford complete relief to the States and that it is not "more burdensome to the defendant than necessary" to provide such relief.[32] *Groupe SEB USA, Inc. v. Euro-Pro Operating LLC*, 774 F.3d 192, 206 (3d Cir. 2014) (internal quotation marks and citations omitted). First, our APA case law suggests that, at the merits stage, courts invalidate—without qualification—unlawful administrative rules as a matter of course, leaving their predecessors in place until the agencies can take further action. *See, e.g.*, *Prometheus Radio*, 652 F.3d at 453-54 & n.25 (vacating procedurally defective rule and leaving the prior rule in effect); *Council Tree Commc'ns, Inc. v. FCC*, 619 F.3d 235, 258 (3d

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[32] Our sister circuit declined to uphold a nationwide injunction concerning the IFRs, but the record before us is substantially more developed than the record before that court. *California II*, 911 F.3d at 584 ("On the present record, an injunction that applies only to the plaintiff states would provide complete relief to them.").

Cir. 2010) (same). Congress determined that rule-vacatur was not unnecessarily burdensome on agencies when it provided vacatur as a standard remedy for APA violations. *See* 5 U.S.C. § 706(2) ("The reviewing court shall . . . hold unlawful and set aside agency action" that is outside an agency's authority, or "without observance of procedure required by law," among other things). While vacatur is the ultimate remedy the States seek, and that is not the relief being granted here, by enjoining enforcement of the Rules we provide a basis to ensure that a regulation that the States have shown likely to be proven to be unlawful is not effective until its validity is finally adjudicated.

Second, a nationwide injunction is necessary to provide the States complete relief. Many individuals work in a state that is different from the one in which they reside. *See* Amici Curiae Massachusetts, et al., Br. at 24 ("Mass. Amici Br.") (stating that 14% of the workforce in New Jersey and 5.4% in Pennsylvania work out of state, comprising more than 800,000 workers in total). An injunction geographically limited to the States alone will not protect them from financial harm, as some share of their residents who work out-of-state will lose contraceptive coverage originally provided through employers in non-enjoined states who will exempt themselves. Women covered by these plans who live in the States will seek state-funded services, and a state specific injunction will not be sufficient to prevent the resulting financial harm.

Out-of-state college attendance further exacerbates the States' injury. As the Moral Exemption points out, "[o]nly a minority of students in higher education receive health insurance coverage from plans arranged by their colleges or universities." 83 Fed. Reg. at 57,564; 83 Fed. Reg. at 57,619. Instead, most of these students remain on their parents' employer-based plans. Mass. Amici Br. at 26. The States host many such students at their colleges. "Each year, for example, Pennsylvania takes in more than 32,000 first-time out-of-state students alone—the second most of any state in the country." Mass. Amici Br. at 25 (citing Nat'l Ctr. For Educ. Statistics, *Residence and Migration of All First-Time Degree/Certificate-Seeking Undergraduates*, Digest of Education Statistics (2017)). In the absence of a nationwide injunction, students attending school in the States may lose contraceptive coverage from their parents' out-of-state plans, again leaving programs within the States to pick up the bill.[33] In light of the impact of these interstate activities, the District Court did not abuse its discretion in concluding that a nationwide injunction was necessary to afford the States complete relief.[34]

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[33] It is also likely that residents of the States will attend out-of-state schools that invoke the Exemptions, and that such students will seek contraceptive services through programs their home states, also giving rise to fiscal injuries to the States that only a nationwide injunction can remedy.

[34] The Government also argues that a nationwide injunction takes a toll on the court system, foreclosing "adjudication by a number of different courts and judges," *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979), thereby preventing legal questions from "percolating" throughout the court system, Gov't Br. at 79-80. The argument has little force in this case. First, other federal courts have examined substantially the same legal issues as we confront here. *See generally Massachusetts*, 923 F.3d 209; California II, 911 F.3d 558. Second, the extensive litigation sur-

## V

For the foregoing reasons, we will affirm the District Court's order granting the nationwide preliminary injunction.

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rounding the Exemption and Accommodation have allowed for an airing of the legal issues. See Petition for Writ of Certiorari at 27, *The Little Sisters of the Poor Jeanne Jugan Residence v. California* (No. 18-1192) ("Further percolation is unnecessary. . . . [T]his issue was adjudicated by ten courts of appeals and dozens of district courts. . . . The arguments have all been aired."). Thus, there is no "percolation" problem here.

## APPENDIX B

## IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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|---|---|
| COMMONWEALTH OF PENNSYLVANIA AND STATE OF NEW JERSEY,<br>Plaintiffs,<br><br>v.<br><br>DONALD J. TRUMP, ALEX M. AZAR II, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, STEVEN T. MNUCHIN, UNITED STATES DEPARTMENT OF THE TREASURY, RENE ALEXANDER ACOSTA, THE UNITED STATES DEPARTMENT OF LABOR, AND THE UNITED STATES OF AMERICA,<br>Defendants,<br><br>LITTLE SISTERS OF THE POOR SAINTS PETER AND PAUL HOME,<br>Defendant-Intervenor. | CIVIL ACTION<br><br>NO. 17-4540 |

## ORDER

**AND NOW**, this 14th day of January, 2019, upon consideration of the Plaintiffs' Second Motion for a Preliminary Injunction (ECF No. 90), Defendants' and Defendant-Intervenor's Responses thereto (ECF Nos. 107 & 108), the Plaintiffs' Reply in Support thereof (ECF No. 118), the Administrative Record (ECF Nos. 23, 47 & 126), Briefs of the Amici Curiae (ECF Nos. 110, 112, 113, 115, 117 & 127), and following a Hearing on Plaintiffs' Motion on January 10, 2019, **IT IS HEREBY ORDERED** that the Motion is **GRANTED**.

It is **FURTHER ORDERED** that Defendants Alex M. Azar II, as Secretary of the United States Department of Health and Human Service; the United States Department of Health and Human Services; Steven T. Mnuchin, as Secretary of the United States Department of Treasury; the United States Department of Treasury; Rene Alexander Acosta, as Secretary of the United States Department of Labor; and the United States Department of Labor;[1] and their officers, agents, servants, employees, attorneys, designees, and subordinates, as well as any person acting in concert or participation with them, are hereby **ENJOINED** from enforcing the following Final Rules across the Nation, pending further order of this Court:

1. Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,536 (Nov. 15, 2018); and

[1] In light of the constitutional concerns associated with enjoining the President of the United States for a claim under the Administrative Procedure Act, this injunction does not apply to the President. See *Franklin v. Massachusetts*, 505 U.S. 788, 801 (1992).

2. Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,592 (Nov. 15, 2018).

The Court has considered the issue of security pursuant to Rule 65(c) of the Federal Rules of Civil Procedure and determines that Defendants will not suffer any financial loss that warrants the need for the Plaintiffs to post security.

BY THE COURT:

/s/Wendy Beetlestone, J.
WENDY BEETLESTONE, J.

**APPENDIX C**

**IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

| | |
|---|---|
| COMMONWEALTH OF PENNSYLVANIA AND STATE OF NEW JERSEY,<br>Plaintiffs,<br>v.<br>DONALD J. TRUMP, ALEX M. AZAR II, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, STEVEN T. MNUCHIN, UNITED STATES DEPARTMENT OF THE TREASURY, RENE ALEXANDER ACOSTA, THE UNITED STATES DEPARTMENT OF LABOR, AND THE UNITED STATES OF AMERICA,<br>Defendants,<br>LITTLE SISTERS OF THE POOR SAINTS PETER AND PAUL HOME,<br>Defendant-Intervenor. | CIVIL ACTION<br>NO. 17-4540 |

# OPINION

**Table of Contents**

Plaintiffs, the Commonwealth of Pennsylvania and the State of New Jersey (collectively "the States"), have sued the United States of America, President Donald J. Trump, the United States Secretary of Health and Human Services Alex M. Azar II, the United States Secretary of the Treasury Steven T. Mnuchin, and the United States Secretary of Labor Rene Alexander Acosta in their official capacities, as well as each of their agencies (collectively "Defendants"), seeking to enjoin enforcement of two Final Rules that grant exemptions to the Affordable Care Act's requirement that health plans cover women's preventive services. The Final Rules "finalize" two Interim Final Rules, which Defendants issued in October 2017 and which this Court enjoined soon thereafter, see *Pennsylvania v. Trump*, 281 F. Supp.3d 553, 585 (E.D. Pa. 2017). On November 15, 2018, while their appeal of that preliminary injunction was pending, Defendants promulgated the Final Rules currently before the Court. The States move to enjoin enforcement of the Final Rules arguing that, like the IFRs before them, the Final Rules violate a variety of constitutional and statutory provisions. For the reasons set forth below, Plaintiffs' Second Motion for a Preliminary Injunction shall be granted.

## I. Background[1]

Although the relevant factual and procedural history of this dispute has been laid out at length before, s*ee id.* at 560-64, that background information is recounted here for the sake of clarity.

### A. Contraceptive Mandate

In March 2010, Congress enacted the Affordable Care Act. See Patient Protection and Affordable Care Act ("ACA"), Pub L. No. 111-148, 124 Stat. 119 (2010). A provision of the ACA, the Women's Health Amendment, mandated that insurance providers cover preventive health services and screenings for women without cost-sharing responsibilities. Specifically, the Women's Health Amendment requires that "[a] group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements . . . with respect to women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by the Health Resources and Services Administration ["HRSA"] for purpose of this paragraph." 42 U.S.C. § 300gg-13(a)(4). This requirement applies to all health insurers offering individual or group insurance, as well as all group health plans, with an exception for certain "grandfathered" plans. 42 U.S.C. § 18011 (exempting "grandfathered" plans); see *also* 29 C.F.R. § 2590.715- 1251 (2010).

[1] The factual statements found here and elsewhere in the opinion constitute this Court's findings of fact, as required under Rule 52(a) of the Federal Rules of Civil Procedure, regardless of any heading or lack thereof.

Rather than enumerate the preventive services to be covered by the mandate, Congress delegated that decision to HRSA, which is an agency of Defendant Department of Health and Human Services ("HHS"). HRSA, in turn, commissioned the then-named Institute of Medicine ("the Institute"), to convene a panel of experts to provide recommendations.[2] On July 19, 2011, the Institute issued its report, recommending that the ACA cover "the full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity." Institute of Medicine, *Clinical Prevention Services for Women: Closing the Gaps*, at 109-10 (2011).

On August 1, 2011, HRSA issued its preventive care guidelines ("2011 Guidelines"), which adopted the Institute's recommendations. See HRSA, *Women's Preventive Services Guidelines*, *available at* https://www.hrsa.gov/womens-guidelines/index.html.[3] The 2011 Guidelines hewed to the Institute's report, defining preventive care to include all FDA-approved "contraceptive methods, sterilization procedures, and patient education and counseling." *Id.*

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[2] The Institute, renamed the National Academy of Medicine in 2015, is an arm of the National Academy of Sciences, an organization that Congress established for the explicit purpose of furnishing advice to the federal government. See *Pub. Citizen v. Dep't of Justice*, 491 U.S. 440, 460 n.11 (1989).

[3] The Guidelines were updated in 2016 but continue to define "preventive services" to include contraceptive services and counseling. See *Updating the HRSA-Supported Women's Preventive Services Guidelines*, 81 Fed. Reg. 95,148, 95,149 (Dec. 27, 2016).

Under the Women's Health Amendment, "non-grandfathered group health plans and health insurance issuers are required to provide coverage consistent with the HRSA Guidelines, without cost sharing." *Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act*, 77 Fed. Reg. 8,725, 8,725 (Feb. 15, 2012). Thus these interlocking statutory and regulatory requirements created the so-called "Contraceptive Mandate."

### B. Regulatory Action to Accommodate Religious Objections

At the same time, and based on "considerable feedback," HHS, the Department of Labor, and the Department of the Treasury (collectively "the Agencies") found it was "appropriate that HRSA, in issuing [the 2011] Guidelines, take[] into account the effect on the religious beliefs of certain religious employers if coverage of contraceptive services were required." *Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act*, 76 Fed. Reg. 46,621, 46,623 (Aug. 3, 2011). The Agencies therefore provided HRSA with "additional discretion to exempt certain religious employers from the Guidelines where contraceptive services are concerned." *Id.*

On August 1, 2011, the Agencies promulgated an interim final rule exempting certain religious employers from providing contraceptive services. *Id.* Under the exemption, a "religious employer" could be exempt from the Contraceptive Mandate only if it: (1) had the inculcation of religious values as its purpose; (2) primarily employed people who shared its religious tenets; (3) primarily served persons who shared its religious tenets; and (4) was a church, its integrated auxiliary, or a convention or association of a church exempt from taxation under the Internal Revenue Code. *Id.* On February 15, 2012, after considering more than 200,000 responses to this interim final rule, the Agencies issued a final rule adopting the "religious employer" definition. 77 Fed. Reg. at 8,725.

On March 21, 2012, the Agencies issued a notice of proposed rulemaking requesting comments on "alternative ways of providing contraceptive coverage without cost sharing in order to accommodate non-exempt, non-profit religious organizations with religious objections to such coverage." *Certain Preventive Services Under the Affordable Care Act*, 77 Fed. Reg. 16,501, 16,503 (March 21, 2012). After receiving and considering over 400,000 comments, the Agencies issued their final rule on July 2, 2013. *Coverage of Certain Preventive Services Under the Affordable Care Act*, 78 Fed. Reg. 39,870, 39,871 (July 2, 2013). The final rule had two noteworthy effects.

First, the rule "eliminate[ed] the first three prongs and clarif[ied] the fourth prong of the definition" of "religious employer" adopted in 2012. *Id.* at 39,874. Under the new definition, an entity qualified as a "religious employer" so long as it "is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (iii)" of the Internal Revenue Code, which applies to "churches, their integrated auxiliaries, and conventions or associations of churches, as well as to the exclusively religious activities of any religious order." *Id.*

Second, the rule established an accommodation for "eligible organizations" with religious objections to providing contraceptive coverage. *Id.* The rule defined an "eligible organization" as one that: "(1) [o]pposes providing coverage for some or all of the contraceptive services required to be covered . . . ; (2) is organized and operates as a nonprofit entity; (3) holds itself out as a religious organization; and (4) self-certifies that it satisfies the first three criteria." *Id.* An eligible organization was required to provide a copy of the self-certification to its insurance provider, which then would provide contraceptive coverage to the organization's employees. *Id.* at 39,876. Thus an eligible organization that self-certified as such was "not required to contract, arrange, pay, or refer for contraceptive coverage," but its "plan participants and beneficiaries [would] still benefit from separate payments for contraceptive services without cost sharing or other charge," consistent with the Contraceptive Mandate. *Id.* at 39,874.

### C. *Hobby Lobby & Wheaton College*

Meanwhile, a host of legal challenges to the Contraceptive Mandate progressed through the federal courts, several of which eventually reached the Supreme Court.

On June 30, 2014, the Supreme Court issued its opinion in *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014). There, three closely-held corporations challenged the Contraceptive Mandate. *Id.* at 2765. The Supreme Court held that the application of the Contraceptive Mandate to the organizations violated the Religious Freedom Restoration Act, 42 U.S.C. § 2000bb-1 ("RFRA"), because the Contraceptive Mandate imposed a substantial burden on the plaintiffs' religious exercise and was not the "least restrictive means" of guaranteeing cost-free access to certain methods of contraception. 134 S. Ct. at 2780-82. The Supreme Court found the existence of the accommodation supported its conclusion that the Contraceptive Mandate was not the "least restrictive means": "HHS itself has demonstrated that it has at its disposal an approach that is less restrictive than requiring employers to fund contraceptive methods that violate their religious beliefs HHS has already established an accommodation for nonprofit organizations with religious objections." *Id.* at 2782. Nevertheless, the Supreme Court refrained from deciding "whether an approach of this type"—meaning the accommodation—"complies with RFRA for purposes of all religious claims." *Id.*

A few days later, the Supreme Court issued an order in a related case, *Wheaton College v. Burwell*, 134 S. Ct. 2806 (2014) (per curiam). There, Wheaton College, an organization eligible for the accommodation, sought an injunction "on the theory that its filing of a self-certification form [would] make it complicit in the provision of contraceptives by triggering the obligation for someone else to provide the services to which it objects." *Id.* at 2808 (Sotomayor, J., dissenting). The Supreme Court granted the injunction, permitting Wheaton College to "inform[] the Secretary of Health and Human Services in writing that it has religious objections to providing coverage for contraceptive services"—that is, the college did not have to "use the [self-certification] form prescribed by the [g]overnment." *Id.* at 2807 (per curiam). The Supreme Court warned, however, that the "order should not be construed as an expression of the Court's views on the merits." *Id.*

### D. Regulatory Response to *Hobby Lobby* & *Wheaton College*

The Agencies responded to *Hobby Lobby* and *Wheaton College* by issuing a notice of proposed rulemaking "amend[ing] the definition of an eligible organization [for purposes of the accommodation] to include a closely held for-profit entity that has a religious objection to providing coverage for some or all of the contraceptive services otherwise required to be covered." *Coverage of Certain Preventive Services Under the Affordable Care Act*, 79 Fed. Reg. 51,118, 51,121 (Aug. 27, 2014). Furthermore, the Agencies issued an interim final rule, effective immediately, that provided "an alternative process" for eligible organizations to self- certify "consistent with the Wheaton order." *Coverage of Certain Preventive Services Under the Affordable Care Act*, 79 Fed. Reg 51,092, 51,094-96 (Aug. 27, 2014). On July 14, 2015, the Agencies issued a rule that finalized the extended accommodation and alternative self- certification process. *Coverage of Certain Preventive Services Under the Affordable Care Act*, 80 Fed. Reg. 41,318, 41,323-24 (July 14, 2015).

### E. *Zubik* Remand & Impasse

On May 16, 2016, the Supreme Court issued its third decision regarding the Contraceptive Mandate. In *Zubik v. Burwell*, 136 S. Ct. 1557 (2016) (per curiam), several organizations eligible for the accommodation challenged the self-certification process on the grounds that the requirement to submit a notice either to their insurer or the federal government violated RFRA. *Id.* at 1559. The Supreme Court declined to reach the merits of the dispute, requesting instead "supplemental briefing from the parties addressing 'whether contraceptive coverage could be provided to petitioners' employees, through petitioners' insurance companies, without any such notice from petitioners.'" *Id.* at 1559-60. After the parties agreed that "such an option [was] feasible," the Supreme Court remanded to afford them "an opportunity to arrive at an approach going forward that accommodates petitioners' religious exercise while at the same time ensuring that women covered by petitioners' health plans receive full and equal health coverage, including contraceptive coverage." *Id.* at 1560 (internal quotation marks omitted). Again, though, the Court "express[ed] no view on the merits of the cases," and refrained from "decid[ing] whether petitioners' religious exercise has been substantially burdened, whether the [g]overnment has a compelling interest, or whether the current regulations are the least restrictive means of serving that interest." *Id.*

Following the remand the Agencies reached an impasse. After reviewing over 50,000 comments submitted in response to a request for information, the Agencies concluded that there was "no feasible approach . . . at this time that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage." Dep't of Labor, *FAQs About Affordable Care Act Implementation Part 36*, at 4 (2016), *available at* https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf.

**F. 2017 IFRs & First Preliminary Injunction**

On May 4, 2017, President Donald Trump issued an Executive Order entitled "Promoting Free Speech and Religious Liberty." Exec. Order No. 13798, 82 Fed.

Reg. 21,675 (May 4, 2017). The Order directed the Agencies to "consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive-care mandate promulgated under [the Women's Health Amendment]." *Id.* at § 3.

On October 6, 2017, aiming to be "[c]onsistent with the President's Executive Order and the Government's desire to resolve the pending litigation and prevent future litigation from similar plaintiffs," *Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act*, 82 Fed. Reg. 47,792, 47,799 (Oct. 13, 2017), the Agencies issued two, new IFRs, referred to as the Religious Exemption IFR and the Moral Exemption IFR. See *id.* at 47,792 ("Religious Exemption IFR"); *Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act*, 82 Fed. Reg. 47,838, 47,838 (Oct. 13, 2017) ("Moral Exemption IFR") (collectively, "the IFRs").

The IFRs made several significant changes to the prior exemption and accommodation framework.[4] For one, the Moral Exemption IFR made the exemption

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[4] The following is not an exhaustive list of the changes enacted by the IFRs, and subsequently the Final Rules. For example, the IFRs also changed the level at which exemptions are to be applied. So, whereas before the availability of an exemption was to be "'determined on an employer by employer basis,'" the IFRs provide that an exemption "will be determined on a plan basis." 82 Fed. Reg. at 47,810. The effect of this change, according to the States, is that an employer may disregard the Contraceptive Mandate by adopting a group health plan "established or maintained" by an objecting organization, *id.*, even if the employer itself does not hold a sincere religious or moral objection to contraception.

available to "additional entities"—including for-profit entities that are not publicly traded—that object based on "sincerely held *moral* convictions," without any need for the objection to be grounded in a *religious* objection to contraception. 82 Fed. Reg. at 47,862 (emphasis added). Second, the Religious Exemption IFR significantly broadened the scope of the religious exemption to encompass any non-profit or for-profit entity, whether closely held or publicly traded. 82 Fed. Reg. at 47,810. Third, the IFRs "likewise" expanded eligibility for the accommodation, allowing entities with sincerely held religious or moral convictions to take advantage of the accommodation process. 82 Fed. Reg. at 47,813; 82 Fed. Reg. at 47,849. Fourth, the IFRs made "the accommodation process optional for eligible organizations," such that entities taking advantage of the accommodation would "not be required to comply with a self-certification process." 82 Fed. Reg at 47,808; 82 Fed. Reg. at 47,850. Finally, the IFRs eliminated the requirement to provide notice of an intent to take advantage of the exemption or accommodation—entities that stop providing contraceptive care "do not need to file notices or certifications of their exemption." 82 Fed. Reg. at 47,808; 82 Fed. Reg. at 47,850. Thus the IFRs permit entities with religious or moral objections to forgo providing contraceptive coverage to employees without "fil[ing] notices or certifications of their exemption." 82 Fed. Reg. at 47,838.[5]

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[5] The IFRs note that ERISA requires certain disclosures: "[u]nder ERISA, the plan document provides what benefits are provided to participants and beneficiaries under the plan and, therefore, if an objecting employer would like to exclude all or a subset of contraceptive services, it must ensure that the exclusion is clear in the plan document." 82 Fed. Reg. at 47,838.

The IFRs became effectively immediately. 82 Fed. Reg. at 47,815; 82 Fed. Reg. at 47,855. Rather than engage in advance notice-and-comment procedures, the Agencies requested post-promulgation comments be submitted by December 5, 2017, 60 days after the IFRs went into effect. 82 Fed. Reg. at 47,792; 82 Fed. Reg. at 47,838. The Commonwealth filed suit in the interim seeking to enjoin enforcement of the IFRs, arguing: (1) they failed to comply with the notice-and-comment procedures required by the APA, 5 U.S.C. § 551, *et seq.*; (2) they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" in violation of the substantive provisions of the APA, 5 U.S.C. § 706(2)(A); (3) they violate Title VII of the Civil Rights Act, 42 U.S.C. § 2000e-2, *et seq.*; (4) they violate the Equal Protection Guarantee of the Fifth Amendment, U.S. Const. amend. V; and, (5) they violate the Establishment Clause, U.S. Const. amend. I.[6] This Court granted the preliminary injunction, finding the Commonwealth was likely to succeed on its claims that the IFRs violated both the procedural and substantive strictures of the APA; it did not, however, reach the merits of the other statutory or constitutional claims. See *Pennsylvania*, 281 F. Supp.3d at 585.[7]

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[6] The State of New Jersey was not party to the original Complaint, and thus, not a party to the first motion for a preliminary injunction either.

[7] Following this Court's issuance of a preliminary injunction, several other district courts issued decisions regarding the propriety of the IFRs. *See California v. Health & Human Servs.*, 281 F. Supp.3d 806, 832 (N.D. Cal. 2017) (enjoining the IFRs for violating the procedural requirements of the APA only), *aff'd in part, vacated in part, remanded sub nom.*, *California v. Azar,* 911 F.3d 558, 566 (9th Cir. 2018) (upholding the lower court's conclusion

Defendants subsequently appealed the decision and moved to stay proceedings while the appeal was pending, which this Court granted.[8]

### G. 2018 Final Rules & Second Motion for Preliminary Injunction

On November 15, 2018, while their appeal of the preliminary injunction was pending before the Third Circuit, the Agencies promulgated two new rules that "finalize[d]" the IFRs. *Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act*, 83 Fed. Reg. 57,536, 57,536 (Nov. 15, 2018) ("Final Religious Exemption"); *Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act*, 83 Fed. Reg. 57,592, 57,592 (Nov. 15, 2018) ("Final Moral Exemption"). "In response to public comments," the Agencies made "various changes" to the Final Rules "to clarify the intended scope of the language" in the IFRs. 83 Fed. Reg. at 57,537; 83 Fed. Reg. at 57,593. The changes, however, were largely "non-substantial technical revisions." 83 Fed. Reg. at 57,567. Defendants assert such changes

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on the merits, but striking down the remedy as overbroad); *Massachusetts v. Health & Human Servs.*, 301 F. Supp.3d 248, 266 (D. Mass. 2018) (finding State lacked standing to challenge the IFRs), *app. docketed*, No. 18-1514 (1st Cir. June 6, 2018).

[8] Following the Commonwealth's initial motion for a preliminary injunction, Defendant-Intervenor Little Sisters filed a motion to intervene. The Court denied that motion. *See Pennsylvania v. Trump*, 2017 WL 6206133, at *1 (E.D.Pa. Dec. 8, 2017). On appeal, however, the Third Circuit reversed, remanding the case to permit intervention. *See Pennsylvania v. President United States of Am.*, 888 F.3d 52, 62 (3d Cir. 2018). The Court duly vacated its prior ruling and granted Defendant-Intervenor Little Sisters' motion.

"do not alter the fundamental substance of the exemptions set forth in the IFRs." The Final Rules were scheduled to take effect on January 14, 2019. 83 Fed. Reg. at 57,567; 83 Fed. Reg. at 57,592.

The Commonwealth then sought to lift the stay to challenge the Final Rules. The Court granted the motion,[9] and Pennsylvania—now joined by New Jersey—filed an Amended Complaint and a Second Motion for a Preliminary Injunction, seeking to enjoin enforcement of the Final Rules.[10] The States argue the Final Rules: (1) failed to comply with the notice-and- comment procedures required by the APA; (2) are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" in violation of the substantive provisions of the APA; (3) violate Title VII of the Civil Rights Act; (4) violate the Equal Protection Guarantee of the Fifth Amendment; and, (5) violate the Establishment Clause. It is to the merits of these contentions that the Court now turns.

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[9] While the filing of a notice of appeal is generally "an event of jurisdictional significance—it confers jurisdiction on the court of appeals and divests the district court of its control over those aspects of the case involved in the appeal," *Griggs v. Provident Consumer Disc. Co.*, 459 U.S. 56, 58 (1982),—"[a]n appeal from the grant or denial of a preliminary injunction does not divest the trial court of jurisdiction or prevent it from taking other steps in the litigation while the appeal is pending," 11A Wright & Miller, Fed. Prac. & Pro. § 2962 (3d ed.); *see also In re Merck & Co., Inc. Sec. Litig.*, 432 F.3d 261, 268 (3d Cir. 2005) (observing that the district court retains the power to "modify or grant injunctions" following an appeal).

[10] The Third Circuit stayed Defendants' appeal pending the resolution of the Second Motion for a Preliminary Injunction. *Pennsylvania v. President United States of Am.*, No. 17-3752 (3d Cir. Jan. 9, 2019).

## II. Analysis[11]

### A. Standing

A threshold question is whether the States have standing. Standing is a litigant's ticket to federal court—a constitutional requirement that "limits the category of litigants empowered to maintain a lawsuit in federal court to seek redress for a legal wrong." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016). The States contend that they are properly before the Court because the Final Rules will imminently cause direct harm to their sovereign, quasi-sovereign and proprietary interests. Additionally, they assert that they have *parens patriae* standing to protect the health, safety and well-being of their residents in ensuring that they enjoy access to healthcare services. Defendants, on the other hand, contend that the States have not suffered any legal wrong that would allow them to get through the turnstile into federal court.

"No principle is more fundamental to the judiciary's proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases or controversies." *Simon v. E. Kentucky Welfare Rights Org.*, 426 U.S. 26, 37 (1976). The doctrine of standing "is part of this limitation." *Id.*; see *also Finkleman v. Nat'l Football League*, 810 F.3d 187, 203 (3d Cir. 2016). "[T]he irreducible constitutional minimum of standing contains three elements." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). First, a plaintiff must have suffered an "injury in fact,"

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[11] This section and all others afterwards includes the Court's legal conclusions as required under Rule 52(a) of the Federal Rules of Civil Procedure.

which is "an invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical." *Id.* (internal quotation marks and citations omitted). Second, a plaintiff must show that there is a "causal connection between the injury and the conduct complained of"—that is, the injury must be "fairly traceable" to the "challenged action of the defendant." *Id.* (internal quotation marks omitted). Third, a plaintiff must show that it is "likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Id.* at 561 (internal quotation marks omitted).

As "[t]he party invoking federal jurisdiction," the States "bear[] the burden of establishing these elements." *Id.* And, "[s]ince they are not mere pleading requirements but rather an indispensable part of the plaintiff's case, each element must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, *i.e.*, with the manner and degree of evidence required at the successive stages of the litigation." *Id.* "[A]t the preliminary injunction stage, allegations are"—without more—"not enough to support standing;" rather, the States must "adduce[] evidence demonstrating more than a mere possibility" that the elements of standing are met. *Doe v. Nat'l Bd. of Med. Exam'rs*, 199 F.3d 146, 152-53 (3d Cir. 1999).

**1. Special Solicitude**

This standing inquiry must be made with recognition that States, like Pennsylvania and New Jersey here, "are not normal litigants for the purposes of invoking federal jurisdiction." *Massachusetts v. EPA*, 549 U.S. 497, 518 (2007). They are "entitled to special solicitude in [the] standing analysis" if they have: (1) a procedural right that authorizes them to challenge the conduct at issue; and, (2) a "stake in protecting [their] quasi-sovereign interests." *Id*. at 520; see *also Texas v. United States*, 809 F.3d 134, 151 (5th Cir. 2015), *aff'd by an equally divided Court*, 136 S. Ct. 2271 (2016) (per curiam).

In determining whether the States have met these conditions, both *Massachusetts v. EPA* and *Texas v. United States* are instructive. In *Massachusetts v. EPA*, Massachusetts sued the Environmental Protection Agency ("EPA"), alleging that the EPA had "abdicated its responsibility under the Clean Air Act" when it failed to issue regulations regarding the emission of certain greenhouse gases. 549 U.S. at 505. The EPA challenged Massachusetts' standing to bring the suit, arguing greenhouse gas emissions are a widespread and generalized harm not unique to any specific plaintiff. *Id*. at 517. The Supreme Court nonetheless held that Massachusetts had special solicitude in the standing inquiry to challenge the EPA's inaction: First, Massachusetts had a procedural right under the relevant statute, the Clean Air Act, which allowed it to "challenge agency action unlawfully withheld." *Id*. (citing 42 U.S.C. § 7607(b)(1)). Second, Massachusetts had a quasi-sovereign interest—a "well-founded desire to preserve its sovereign territory" from the effects of global warming because Massachusetts "own[ed] a great deal of the territory alleged to be affected." *Id*. at 519 (internal quotation marks omitted); see *also id*. at 522 (noting affidavits asserting that "rising seas have already begun to swallow Massachusetts' coastal land."). After concluding that Massachusetts was entitled to special solicitude in the standing analysis, the Supreme Court ultimately held that it had Article III standing to sue the EPA based on the injury to its territory stemming from global warming. *Id*. at 526.

In *Texas v. United States*, the Fifth Circuit, relying on *Massachusetts v. EPA*, similarly concluded that Texas and a multitude of other States were entitled to special solicitude in seeking to enjoin implementation of the Deferred Action for Parents of Americans and Lawful Permanent Residents program ("DAPA"). 809 F.3d at 154-55. There, non-citizens in Texas could apply for a driver's license if they presented "documentation issued by the appropriate United States agency that authorizes the applicant to be in the United States." *Id*. at 155 (internal quotation marks omitted). DAPA would have permitted at least 500,000 non-citizens to qualify for these driver's licenses. *Id.* Because Texas subsidized its licenses, it would have lost money for each license issued to a DAPA beneficiary. *Id*. Texas therefore sought injunctive relief to prevent DAPA's implementation. See *id.* at 149.

The Fifth Circuit applied the *Massachusetts v. EPA* framework and concluded that Texas was entitled to special solicitude. First, the Fifth Circuit considered whether the States' challenge was similar in kind to the challenge brought by Massachusetts, and concluded that it was. Both suits turned on the construction of a federal statute that specifically provided for a procedural right to judicial review, and Texas' use of the APA to challenge an "affirmative decision" made by a federal agency was comparable to Massachusetts' use of the judicial review provision in the Clean Air Act to challenge the EPA's inaction. *Id*. at 152. Second, as to the quasi-sovereign interest, the Fifth Circuit held that DAPA imposed "substantial pressure" on Texas to change its laws to avoid bearing further costs from subsidizing additional driver's licenses. *Id*. at 153. The Fifth Circuit thus concluded that Texas, and its fellow plaintiff States, warranted special solicitude in their suit against the federal government under the APA. *Id*. at 154-55.[12]

The Fifth Circuit's reasoning in *Texas v. United States* is persuasive here. Here as there, the States bring suit under the APA to challenge an affirmative action by the federal government. See *Texas*, 809 F.3d at 152. And, the Final Rules—like DAPA—"affect[] the [S]tates' 'quasi-sovereign' interest by imposing substantial pressure on them to change their laws." *Id.* Specifically, they put pressure on provisions of the States' laws that provide state- funded contraceptive care to low-income citizens. As the States show, the Final Rules permit more employers to exempt themselves from the Contraceptive Mandate, which would result in more of the States' women seeking state-

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[12] Defendants here question the binding effect of *Texas v. United States* beyond the facts of that case, given that the Supreme Court summarily affirmed the Fifth Circuit's decision "by an equally divided Court." *United States v. Texas*, 136 S. Ct. 2271 (2016) (per curiam). While an affirmance by an equally divided Supreme Court typically does not constitute binding precedent, *see Eaton v. Price*, 364 U.S. 263, 264 (1960), where the Supreme Court is equally divided on an issue of subject matter jurisdiction, it has determined that the proper course is to remand the issue of jurisdiction to a lower court. *See Silliman v. Hudson River Bridge Co.*, 66 U.S. 582, 584-85 (1861). In other words, if the Supreme Court were equally divided on whether Texas had standing to challenge DAPA, it would have remanded that issue to the Fifth Circuit. The Supreme Court did not, and instead affirmed the Fifth Circuit, indicating that a majority of the Supreme Court decided that Texas had standing to pursue its APA claim. Certainly, if the Supreme Court had determined that Texas did not have standing, it would not have had jurisdiction to hear the case. Even if the affirmance by an equally divided Supreme Court as it relates to subject matter jurisdiction were not binding, the Court is persuaded by the reasoning of the Fifth Circuit in *Texas v. United States* as it pertains to State standing.

funded sources of contraceptive care. The harm to the States' fiscs are "intrusions . . . analogous to pressure to change the law," *id.*, implicating the States' quasi-sovereign interests. See *also Alfred L. Snapp & Son, Inc. v. Puerto Rico*, 458 U.S. 592, 607 (1982) (holding that a State has a "quasi-sovereign interest in the health and wellbeing—both physical and economic—of its residents in general."). The States, then, meet the two conditions outlined in *Massachusetts v. EPA* and shall be accorded special solicitude in the standing analysis.

**2. Article III Standing**

While the States are entitled to special solicitude in the standing analysis, they must nevertheless meet the "irreducible constitutional minimum of standing"—namely, injury in fact, causation, and redressability. *Lujan*, 504 U.S. at 560. In its initial challenge to the IFRs, the Commonwealth satisfied this burden, see *Pennsylvania*, 281 F. Supp.3d at 569, and the same is true of the States' challenge to the Final Rules. See *also California*, 911 F.3d at 571 (finding another group of States had standing to challenge the IFRs).

First, the Final Rules inflict a direct injury upon the States by imposing substantial financial burdens on their coffers. An agency rule that has "a major effect on the states' fiscs" is sufficient to find injury in fact. *Texas*, 809 F.3d at 152; *id.* at 155 ("[Texas] satisfied the first standing requirement by demonstrating that it would incur significant costs in issuing driver's licenses to DAPA beneficiaries."); see *also Wyoming v. Oklahoma*, 502 U.S. 437, 448 (1992) (holding that Wyoming had Article III standing because it undisputedly suffered a "direct injury in the form of a loss of specific tax revenues"); *Danvers Motor Co., Inc. v. Ford Motor*

*Co.*, 432 F.3d 286, 291 (3d Cir. 2005) ("While it is difficult to reduce injury-in-fact to a simple formula, economic injury is one of its paradigmatic forms."). If the Final Rules go into effect, the States will have to increase their expenditures for State funded programs that provide contraceptive services. This is not a speculative harm. As Defendants themselves noted in issuing the IFRs, "there are multiple Federal, State, and local programs that provide free or subsidized contraceptives for low-income women." 82 Fed. Reg. at 47,803. As more of the States' women residents are deprived of contraceptive services through their insurance plans and turn to these State funded programs, the States will be pressed to make greater expenditures to ensure adequate contraceptive care. See Mendelsohn Decl. ¶ 15; Steinberg Decl. ¶¶ 24-25. And although Defendants point out that the States have not yet identified a woman resident who has lost contraceptive coverage due to the Final Rules, the States need not sit idly by and wait for fiscal harm to befall them. See *McNair v. Synapse Group Inc.*, 672 F.3d 213, 223 (3d Cir. 2012) ("When, as in this case, prospective relief is sought, the plaintiff must show that he is 'likely to suffer *future* injury' from the defendant's conduct.") (quoting *City of Los Angeles v. Lyons*, 461 U.S. 95, 105 (1983) (emphasis added)). At bottom, just as Texas' estimated loss due to DAPA supported a finding that Texas suffered an injury in fact, so too does the States' estimated loss due to the Final Rules support a finding that the States have suffered an injury in fact. See *Texas*, 809 F.3d at 155.

Second, the States' financial injury is "fairly traceable" to the issuance of the Final Rules. By their terms, the Final Rules expand the scope of the existing religious exemption rule and allow entities a new rationale for refusing to provide employees with contraceptive coverage if the refusal is "based on sincerely held moral convictions," 83 Fed. Reg. at 57,593. Thus, the Final Rules allow more entities to stop providing contraceptive coverage, which will result in more women residents seeking contraceptive care through State-funded programs. See Mendelsohn Decl. ¶ 15; Steinberg Decl. ¶¶ 24-25. The States have thus shown a causal connection between the Final Rules and their financial injury.

As the Court previously explained, *Pennsylvania v. New Jersey*, 426 U.S. 660 (1976), is not to the contrary. See *also California*, 911 F.3d at 574 (finding *Pennsylvania* did not bar States' challenge to the IFRs on a similar theory of standing). In that case, Pennsylvania voluntarily gave tax credits to Pennsylvania residents who paid taxes in New Jersey, and then proceeded to sue New Jersey, contending that the New Jersey tax injured Pennsylvania's fiscs and was constitutionally impermissible. *Pennsylvania*, 426 U.S. at 662-63. The Supreme Court found that Pennsylvania lacked standing because the injuries to its fiscs were "self-inflicted," resulting, as they did, from a decision of its state legislature to enact a law that incorporated the legislative choices of New Jersey. *Id*. at 664. Here, by contrast, the States' laws funding contraceptive care do not "directly and explicitly" tie the States' finances to another sovereign's law. *California*, 911 F.3d at 574. Rather, the States' described injuries flow from the unilateral decision by the Agencies to issue the Final Rules. See *id.* (finding *Pennsylvania* did control in an analogous challenge); *cf. Texas*, 809 F.3d at 158 ("The fact that Texas sued in response to a significant change in the [federal government's] policies shows that its injury is not self- inflicted."). The States have therefore met the traceability requirement.

Finally, the States have satisfied the redressability requirement. As to the States' procedural claims, enjoining the Final Rules could prompt the Agencies "to reconsider the program, which is all a plaintiff must show when asserting a procedural right." *Texas*, 809 F.3d at 161; s*ee also Massachusetts*, 549 U.S. at 518 (noting that where, as here, a litigant is "vested with a procedural right, that litigant has standing if there is some possibility that the requested relief will prompt the injury-causing party to reconsider the decision that allegedly harmed the litigant"). And, as for the States' substantive claims, enjoining the Final Rules "would prevent [the States'] injury altogether." *Texas*, 809 F.3d at 161.

In sum, the States have established the irreducible constitutional minimum of standing to challenges the Final Rules in federal court.[13]

**B. Venue**

The next question to address is whether the States' choice of venue—the Eastern District of Pennsylvania—is proper. Notwithstanding Defendants' argument to the contrary, it is.

Defendants' argument is grounded in the structure of the venue statute, Section 1391(e)(1) of which provides that in a civil action against an officer of the United States, venue lies "in any judicial district in which . . . the plaintiff resides if no real property is

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[13] Because the States have identified an imminent, direct injury to its state coffers that would result from the Final Rules, there is no need to address whether they have *parens patriae* standing.

involved in the action." 28 U.S.C. § 1391(e)(1). Section 1391(c) defines a party's residence "[f]or all venue purposes," and distinguishes between three, and only three, categories of litigants: "a natural person," "an entity with the capacity to sue and be sued in its common name under applicable law, whether or not incorporated," and "a defendant not resident in the United States." *Id.* at § 1391(c). Because Pennsylvania is neither a natural person nor a non-resident, Defendants argue it must be treated as an entity for purposes of determining residency. Section 1391(c)(2) provides that "if a plaintiff," an entity "shall be deemed to reside . . . only in the judicial district in which it maintains its principal place of business." *Id.* Thus, according to Defendants, Pennsylvania resides only in the Middle District—the district that encompasses Harrisburg, the state capital—because that is where Pennsylvania maintains its principal place of business.

While inventive, Defendants' interpretation of Section 1391(c) is ultimately unpersuasive. See *California*, 911 F.3d at 570 (rejecting the argument); *Alabama v. U.S. Army Corps of Eng'rs,* 382 F. Supp.2d 1301, 1328 (N.D. Ala. 2005) (rejecting a similar argument for an earlier version of the venue statute). Defendants' argument hinges on the assumption that, because Section 1391(c) refers to only three categories of litigants and because a state is neither a natural person nor a non-resident, a state must necessarily be "an entity" for purposes of the venue statute. There are, however, several issues with that assumption.

First, the statute explicitly refers to an entity's incorporation status, indicating "that the term [entity] refers to some organization, not a state." *California*, 911 F.3d at 570. The legislative history confirms that Congress was contemplating "unincorporated associations, such as partnerships and labor unions, and other entities with capacity to sue in their common name," when it defined the residency of unincorporated entities in Section 1391(c). H.R. Rep. No. 112-10, at 21 (2011). There is no indication, however, that Congress intended for that provision to dictate the residency of sovereign States by equating a State with an "unincorporated association[]" like a labor union.

Second, Congress explicitly distinguishes between States and entities within Section 1391. *Compare* 28 U.S.C. § 1391(c) (defining the residency of an "entity"), *with id.* at § 1391(d) ("Residency of corporations in States with multiple districts"). "Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Russello v. United States*, 464 U.S. 16, 23 (1983) (internal quotation marks and citations omitted). Thus, courts typically "refrain from concluding . . . that the differing language in [] two subsections [of a statute] has the same meaning in each." *Id.* Here, Congress's differentiation between "an entity" and "States" within Section 1391 indicates that Congress did not intend to include the latter within the definition of the former.

Finally, reading Section 1391 as Defendants suggest would yield an absurd result. As several courts have observed, an interpretation that "limit[s] residency to a single district in the state would defy common sense," because "[a] state is ubiquitous throughout its sovereign borders." *California*, 911 F.3d at 570;

*Alabama*, 382 F. Supp.2d at 1329 ("[C]ommon sense dictates that a state resides throughout its sovereign borders").[14]

Thus, the Court will follow the lead of the Ninth Circuit in concluding that "the statute . . . dictates that a state with multiple judicial districts 'resides' in every district within its borders." *California*, 911 F.3d at 570. Venue is therefore proper in the Eastern District of Pennsylvania.[15]

**C. Preliminary Injunction**

Because the States have established standing to bring their claims into federal court and that this is a proper venue to hear those claims, the Court now

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[14] The unreported district court cases that Defendants rely upon are not to the contrary. *See Gaskin v. Pennsylvania*, 1995 WL 154801, at *1 (E.D. Pa. Mar. 30, 1995); *Bentley v. Ellam*, 1990 WL 63734, at *1 (E.D. Pa. May 8, 1990). Both *Gaskin* and *Bentley* discuss the residency of state agencies or officials, which is different in kind from the residency of a sovereign State itself.

[15] Section 1391(e) also provides that venue is proper in a civil action against an officer of the United States, where "a substantial part of the events or omissions giving rise to the claim occurred." 28 U.S.C. § 1391(e). Because the Court finds Pennsylvania resides throughout the State, it need not address the States' alternative argument that venue is proper because "a substantial part of the events" giving rise to their claim occurred here.

Relatedly, New Jersey's residency does not bear on the question of because "in an action against the federal government or an agent thereof [t]here is no requirement that all plaintiffs reside in the forum district." *Exxon Corp. v. FTC*, 588 F.2d 895, 899-90 (3d Cir. 1978); *Superior Oil Co. v. Andrus*, 656 F.2d 33, 37 n.7 (3d Cir. 1981) ("[O]nly one plaintiff need satisfy the residency requirement of [Section 1391(e)].").

turns to the merits of the preliminary injunction motion.

#### 1. Legal Standard

A preliminary injunction is an extraordinary remedy; it "should be granted only in limited circumstances." *American Tel. & Tel. Co. v. Winback & Conserve Program, Inc.*, 42 F.3d 1421, 1426-27 (3d Cir. 1994). "A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter v. NRDC*, 555 U.S. 7, 20 (2008). The first two are the "most critical factors: [a movant] must demonstrate that it can win on the merits (which requires a showing significantly better than negligible but not necessarily more likely than not) and that it is more likely than not to suffer irreparable harm in the absence of preliminary relief." *Reilly v. City of Harrisburg*, 858 F.3d 173, 179 (3d Cir. 2017), *as amended* (June 26, 2017) (internal quotation marks omitted). "If these gateway factors are met, a court then considers the remaining two factors and determines in its sound discretion if all four factors, taken together, balance in favor of granting the requested preliminary relief." *Id.*

#### 2. Likelihood of Success on the Merits

In demonstrating the likelihood of success on the merits, a plaintiff need not show that it is more likely than not that it will succeed. *Singer Mgmt. Consultants, Inc. v. Milgram*, 650 F.3d 223, 229 (3d Cir. 2011) (en banc). Instead, all a plaintiff must show is "a *likelihood* of success on the merits (that is, a reasonable chance, or probability, of winning) to be granted relief." *Id.* (emphasis in original).

**a. APA Procedural Claim**

The States argue that the Final Rules should be enjoined because Defendants failed to comply with the procedural requirements of the APA.

The APA generally requires that, when promulgating regulations, administrative agencies meet a set of procedural requirements, called notice-and-comment rulemaking. See 5 U.S.C. § 553. Agencies must: issue a general notice of proposed rulemaking, see *id.* at § 553(b); "give interested persons an opportunity to participate in the rule making through submission of written data, views or arguments . . ." *id.* at § 553(c); and, "[a]fter consideration of the relevant matter presented, . . . incorporate in the rules adopted a concise general statement of their basis and purpose," *id.*

Notice-and-comment rulemaking serves two distinct purposes—it both "give[s] the public an opportunity to participate in the rule-making process," and "enables the agency promulgating the rule to educate itself before establishing rules and procedures which have a substantial impact on those regulated." *Texaco, Inc. v. Fed. Power Comm'n*, 412 F.2d 740, 744 (3d Cir. 1969). Nevertheless, there are limited exceptions to the requirement that all rules be issued pursuant to notice-and-comment rulemaking, such as when an agency has "good cause" to forgo the strictures of notice-and-comment rulemaking, 5 U.S.C. § 553(b), or when a subsequent act of Congress abrogates the APA's procedural requirements, *id.* at § 559.

In issuing the IFRs, the Agencies failed to meet the various requirements of notice-and- comment rulemaking. See *Pennsylvania*, 281 F. Supp.3d at 570. Defendants argued, however, that the IFRs were not procedurally invalid because they fell under one (or more) of the limited exceptions to notice-and-comment rulemaking. *Id.* at 571. The Court found otherwise and enjoined the IFRs for violating the procedural strictures of Section 553. *Id.* at 576; see *also California*, 281 F. Supp.3d at 829 (enjoining the IFRs for violating the procedural requirements of the APA)*, aff'd in part, vacated in part*, *California*, 911 F.3d at 575 (upholding the conclusion that the IFRs violated the APA).

While Defendants continue to maintain that the IFRs were procedurally valid,[16] they now argue that, even assuming the IFRs were procedurally improper, the subsequent action taken by the Agencies in promulgating the Final Rules satisfied notice-and-comment requirements, and thus the Final Rules comply with the APA. The States' response is two-fold. First, they argue that the Agencies notice-and-comment procedures fell short of the APA's requirements because the Agencies did not adequately respond to significant comments in their statement of the basis and purpose of the Final Rules. Second, the States contend that, no matter the Agencies' subsequent actions, the procedural defects that characterized the issuance of the

[16] The Court, for the reasons stated in its prior opinion, again finds the Agencies' position unpersuasive, *see Pennsylvania*, 281 F. Supp.3d at 570, and therefore declines Defendants' invitation to revisit its prior holding. See *Hayman Cash Register Co. v. Sarokin*, 669 F.2d 162, 165 (3d Cir. 1982) ("Under the law of the case doctrine, once an issue is decided, it will not be relitigated in the same case, except in unusual circumstances.").

IFRs fatally taint the Final Rules. These arguments are considered *seriatim*.

**i. Inadequate Response to Comments**

The States argue that the Agencies' issuance of the Final Rules failed to meet the requirements of notice-and-comment rulemaking by not responding to all "vital questions[] raised by comments which are of cogent materiality." *United States v. Nova Scotia Food Prod. Corp.*, 568 F.2d 240, 252 (2d Cir. 1977). The APA requires federal agencies to "consider and respond to significant comments received during the period for public comment." *Perez v. Mortg. Bankers Ass'n*, 135 S. Ct. 1199, 1203 (2015). The requirement, however, is not "particularly demanding." *Nazareth Hosp. v. Sec'y U.S. Dep't of Health & Human Servs.,* 747 F.3d 172, 185 (3d Cir. 2014) (quoting *Pub. Citizen, Inc. v. FAA,* 988 F.2d 186, 197 (D.C. Cir. 1993)). All that is required is a response that "'demonstrates that the [agency] considered and rejected' the arguments." *Id.* (quoting *Covad Commc'ns Co. v. FCC,* 450 F.3d 528, 550 (D.C. Cir. 2006)).

The States contend that the Agencies failed to clear this relatively low bar, pointing to several examples of comments that purportedly received an inadequate response: comments that discuss the scientific evidence of the harm to the health and economic security of women that would result from the Final Rules, 83 Fed. Reg. at 57,555-56; comments that assert the broad religious and moral exemptions will cause women to lose contraceptive coverage, *id.* at 57,548- 49; comments that argue the exemptions violate the ACA prohibition on regulations that create barriers to medical care, *id.* at 57,551-52; and, specifically, a comment submitted by various States—including Pennsylvania and New Jersey—regarding the medical risks associated with pregnancy, *id*. at 57,555.

For each example, however, a review of the Final Rules demonstrates that the Agencies acknowledged the comments and provided an explanation as to why the Agencies did (or did not) amend the Final Rules based on the comment. See 83 Fed. Reg. at 57,548, 57,551, 57,555. While the Agencies' explanations are not always the picture of clarity, they meet the not "particularly demanding" requirement, *Nazareth Hosp*., 747 F.3d at 185, that the Agencies "consider and respond to significant comments received during the period for public comment," *Perez*, 135 S. Ct. at 1203. Put differently, the Final Rules "demonstrate [to a commenter] that the [the Agencies] considered and rejected, the arguments" put forth by a commenter, which is "all that the [APA] requires." *Nazareth Hosp*., 747 F.3d at 185 (internal quotation marks omitted).

Thus, the States are unlikely to succeed on the merits of their argument that, in promulgating the Final Rules, the Agencies' actions failed to meet the requirements of notice- and-comment rulemaking.[17]

**ii. IFRs Taint the Final Rules**

The States maintain that, even if the Agencies complied with the requirements of notice- and-comment rulemaking in promulgating the Final Rules, the failure to do so in promulgating the IFRs fatally infected

[17] The States' argument is limited to the claim that the Agencies failed to adequately respond to significant comments. The States do not argue, for example, that the notice provided was inadequate. See 5 U.S.C. § 552(b).

the process such that the Final Rules should also be held invalid.

Generally, "the period for comments after promulgation cannot substitute for the prior notice and comment required by the APA." *Sharon Steel. Corp. v. EPA*, 597 F.2d 377, 381 (3d Cir. 1979). The Circuit courts however, diverge on the procedural validity of a final rule that follows an IFR promulgated in a procedurally flawed manner—that is, the question of whether a "procedural defect that taints the original, interim-final rule carr[ies] over to the succeeding final rule." Kristin E. Hickman & Mark Thomson, *Open Minds and Harmless Errors: Judicial Review of Post-promulgation Notice and Comment*, 101 Cornell L. Rev. 261, 267 (2016) (discussing various approaches taken by the Circuit courts); *compare Salman Ranch, Ltd. v. Comm'r*, 647 F.3d 929, 940 (10th Cir. 2011) ("While the . . . temporary regulations were issued without notice and comment, now that the regulations have issued in final form [after notice and comment], these arguments are moot . . .") (internal quotation marks omitted), *rev'd on other grounds, Salman Ranch, Ltd. v. Comm'r*, 566 U.S. 971 (2012), *with Air Transp. Ass'n of Am. v. Dep't of Transp.*, 900 F.2d 369, 379 (D.C. Cir. 1990) ("Although we have suggested that there might be circumstances in which 'defects in an original notice [could] be cured by an adequate later notice' and opportunity to comment, we have emphasized that we could reach such a conclusion only upon a compelling showing that 'the agency's mind remain[ed] open enough at the later stage.' The FAA has not come close to overcoming the presumption of closed-mindedness in this case.") (quoting *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1323 (D.C. Cir. 1988)), *vacated on other grounds,* 498 U.S.

1077 (1991). For its part, the Third Circuit has evidenced a deep skepticism towards the curative powers of post-promulgation notice-and-comment procedures, see *NRDC v. EPA*, 683 F.2d 752, 767-68 (3d Cir. 1982); *United States v. Reynolds*, 710 F.3d 498, 519 (3d Cir. 2013); *accord Sharon Steel. Corp*., 597 F.2d at 381, which warrants a conclusion that the States are likely to succeed on the claim that the procedural faults that characterized the issuance of the IFRs fatally tainted the Final Rules such that the issuance of the Final Rules violated the APA.

The Third Circuits' decision most directly on point is *NRDC v. EPA*. There, the NRDC challenged EPA action that indefinitely postponed the effective date of certain Clean Water Act amendments. *NRDC*, 683 F.2d at 757. The EPA did not engage in notice-and-comment procedures before acting to postpone the implementation of the amendments.[18] *Id.* at 756. After NRDC initiated litigation challenging the agency's action, the EPA issued a notice of proposed rulemaking, seeking comments on whether the agency should issue a rule further postponing the effective date. *Id.* at 757. After going through notice-and-comment procedures, the EPA then issued a final rule implementing some of the amendments, while further postponing the most controversial bits. *Id.* Nevertheless, NRDC maintained its challenge to the EPA's initial action to postpone the effective date. The Third Circuit rejected the

[18] The EPA argued that the initial action to postpone was not a "rule" under the APA, and thus did not require notice-and-comment procedures. *NRDC*, 683 F.2d at 761. The Third Circuit rejected that argument, holding the EPA's action postponing the effective date qualified as a rule, requiring notice-and-comment procedures. *Id.*

EPA's argument that its notice- and-comment procedures *after* the initial action to postpone "cured" any failure to engage in such procedures *before* the initial action, and held the initial action postponing the effective date was procedurally invalid. *Id.* at 767.

Critical to this dispute, however, the Third Circuit further held that, even though the NRDC did not challenge the final rule—that is, the rule promulgated following notice-and- comment procedures—the final rule "was likewise invalid." *Id.* at 768. The court of appeals explained that the appropriate remedy for the EPA's failure to engage in notice-and-comment rulemaking before taking its initial action required holding *both* the initial action and the subsequent, final rule "ineffective." *Id.* at 767. EPA's notice-and-comment procedures "could not serve as the procedural mechanism" for the final rule because "that rulemaking [could not] replace one on the question of whether the amendments should be postponed in the first place." *Id.* That is, if the EPA had engaged in notice-and-comment procedures before initially acting to postpone the effective date, then "the question to be decided in the [subsequent] rulemaking"—the rulemaking that complied with notice-and-comment procedures—"would have been whether the amendments . . . should be suspended, and not whether they should be further postponed." *Id.* The Third Circuit warned that:

> To allow the APA procedures in connection with the further postponement to substitute for APA procedures in connection with an initial postponement would allow EPA to substitute post-promulgation notice and comment procedures for pre-promulgation notice and comment procedures at

> any time by taking an action without complying with the APA, and then establishing a notice and comment procedure on the question of whether that action should be continued We cannot countenance such a result.

*Id.*

That reasoning applies with equal force here. The Agencies issued the IFRs without engaging in notice-and-comment rulemaking. As in *NRDC*, the issuance of the procedurally defective IFRs fundamentally changed the "question to be decided in the [subsequent] rulemaking"—instead of asking whether substantial expansions to the exemption and accommodation should be made *at all*, the Agencies solicited comments on whether those changes should be *finalized*. Thus, the subsequent "rulemaking on [finalizing the IFRs] could not serve as the procedural mechanism," for the Final Rules because "that rulemaking [could not] replace one on the question of whether" the Agencies should broaden the existing exemption and accommodation "in the first place." *Id.* The Agencies are, in essence, engaging in precisely the behavior that the Third Circuit warned against in *NRDC*: "substitute[ing] post-promulgation notice and comment procedures for pre-promulgation notice and comment procedures . . . by taking an action without complying with the APA, and then establishing a notice and comment procedure on the question of whether that action should be continued." *Id.* The Court, like the Third Circuit, "cannot countenance such a result." *Id.*

Defendants and Defendant-Intervenor advance several arguments to the contrary, none of which are ultimately persuasive. For one, Defendants argue that

*NRDC* is not on all fours with this case and so "provides no support for the Plaintiffs' procedural challenge." Defendants are correct that *NRDC* differs factually from the case at hand: there the NRDC challenged only the initial action, here the States challenged both the IFRs and the Final Rules. But, even though the plaintiff did not challenge the final rule in *NRDC*, the Third Circuit held both the initial action to postpone and the subsequent rule procedurally invalid. In reaching that determination, the Third Circuit rejected the notion—advanced by the Agencies here—that subsequent notice-and- comment rulemaking procedures "cured" the failure to engage in such procedures "in the first place." *Id*. at 767-78. Both the holding and the reasoning given for that holding are binding on this Court. See *Tate v. Showboat Marina Casino P'ship*, 431 F.3d 580, 582 (7th Cir. 2005) (Posner, J.) ("[T]he holding of a case includes, besides the fact and the outcome, the reasoning essential to that outcome."); see *also IFC Interconsult, AG v. Safeguard Int'l Partners, LLC*, 438 F.3d 298, 311 (3d Cir. 2006) (quoting Judge Posner's definition approvingly). Because the Third Circuit's reasoning invalidating the subsequent rule was essential to the holding, and because that reasoning applies with equal force to the promulgation of the Final Rules, that reasoning controls here.

Next, Defendants argue that the States suffered no procedural injury because they had an opportunity to submit a comment in response to the IFRs, an opportunity that the States "admit" to taking advantage of. The problem for Defendants is that the EPA made the exact argument to the Third Circuit in *NRDC*, which the court of appeals flatly rejected. *NRDC*, 683 F.2d at 768. As the Third Circuit explained, it did not matter that "notice and comment were provided in connection with the proposal that the amendments be further postponed, and NRDC was able to make all of the arguments in connection with the further postponement that NRDC would have made in connection with the initial postponement." *Id.* The problem was that the initial, procedurally defective action fundamentally changed the question to be presented in the subsequent rulemaking, prejudicing NRDC, which "'must come hat-in-hand and run the risk that the decisionmaker is likely to resist change.'" *Id.* at 768 (quoting *Sharon Steel*, 597 F.2d at 381). Here, the procedurally invalid IFRs similarly changed the question to be presented in the subsequent rulemaking, prejudicing the States' ability to have their comments heard by an impartial decisionmaker. *Cf. Wagner Elec. Corp. v. Volpe*, 466 F.2d 1013, 1020 (3d Cir. 1972) ("Section [553(b)] of the [APA] requires notice *before* rulemaking, not after. The right of interested persons to petition for the issuance, amendment or repeal of a rule, granted in [5 U.S.C. § 553(e)], is neither a substitute for nor an alternative to compliance with the mandatory notice requirements of [5 U.S.C. § 553(b)].") (emphasis in original).

Defendant-Intervenor's attempt to distinguish away the reasoning of *NRDC* fares no better. It argues the court of appeals' reasoning does not control because, while "unique circumstances" existed in *NRDC* "to establish prejudice," no such circumstances are present here. Specifically, Defendant-Intervenor argues that the Third Circuit invalidated the final rule in *NRDC* because of the "asymmetry between using an interim rule to repeal a rule promulgated with prior notice and comment," whereas, here, the Final Rules are not "an abrupt change in federal policy" because the Final Rules do not rescind the Contraceptive Mandate. According to Defendant-Intervenor, that makes this case "readily distinguishable from *NRDC*."

The argument is premised on a misreading of *NRDC*. The Third Circuit did not invalidate the EPA action because of the degree of change affected by the procedurally invalid action. Rather, it held that the subsequent notice-and-comment rulemaking "[could not] replace [a rulemaking] on the question of whether the amendments should be postponed in the first place." *NRDC*, 683 F.2d at 768. More fundamentally, the court of appeals did not rest its decision on the existence of any "unique circumstances," as Defendant-Intervenor suggests. Instead, the Third Circuit voiced a general admonition against the practice of using post- promulgation procedures to cure pre-promulgation procedural flaws. *Id.* As discussed, the reasoning underpinning that warning informs the result here.

Defendant-Intervenor also advances an altogether different argument. It points out that the Agencies "created the [Contraceptive] Mandate via a series of IFRs without notice and comment," suggesting that the Final Rules are procedurally valid because the Agencies followed similar procedures in the past. The Court rejected a version of this argument last go around. See *Pennsylvania*, 281 F. Supp.3d at 573 n.8. Whether a party could have brought a successful challenge to the procedures followed in the past is not before the Court—what is at issue here is whether the procedures the Agencies followed in issuing the Final Rules violated the APA. *Id.* (explaining that the IFRs were "not identical to prior regulations" because "they make significant changes in the law, and the Supreme Court did not require immediate action"). The same flawed reasoning characterizes Defendant-Intervenor's related argument that invalidating the Final Rules would "cast a pall on thousands of regulations," because, according to the Government Accountability Office, 35% of all major rules were finalized with post-IFR notice-and-comment procedures. Obviously, those regulations are not currently before this Court, and, accordingly, the Court is not asked—and thus, cannot decide—whether the specific procedures employed in promulgating those regulations were defective.

The States are likely to prevail on their claim that the issuance of the Final Rules violated the procedural requirements of the APA in that the procedural defect that characterized the IFRs fatally tainted the issuance of the Final Rules. That is so, regardless of whether the procedure followed by the Agencies in the Final Rules may otherwise meet the requirements of notice-and- comment rulemaking.[19]

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[19] As noted, other courts of appeals employ other approaches when evaluating whether a procedural defect in an interim-rule fatally infects a final rule issued after notice-and-comment procedures are followed—one example being the "open mind" approach. See, *e.g.*, *Air Transp. Ass'n of Am.*, 900 F.2d at 379 (employing the "open mind standard"). While it has never adopted this approach, the Third Circuit in *Reynolds* indicated that whether a promulgating agency "maintained a flexible and open-minded attitude towards" an interim rule is a relevant consideration in determining whether an APA violation occurred generally. 710 F.3d at 519.

Even under the more flexible "open mind standard," however, the States would likely succeed on the merits of their procedural claim. As the D.C. Circuit has explained, while "defects in an original notice could be cured by an adequate later notice and opportunity to comment," the remedial measures cure the earlier lapses only if the promulgating agency makes "a compelling showing that the agency's mind remained open enough at the

**b. APA Substantive Claim**

The States also contend that the Final Rules violate the substantive requirements of the APA. As the Court has previously noted, the breadth of the exemptions set out in the IFRs, and now the Final Rules, is remarkable. The Final Religious Exemption allows all non-profit and for-profit entities, whether closely held or publicly traded, to deny contraceptive coverage based on sincerely held religious beliefs. The Final Moral Exemption allows any non-profit or for- profit

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later stage." *Air Transp. Ass'n of Am.*, 900 F.2d at 379 (internal quotation marks omitted). That is, "it is the agency's burden to persuade the court that it has accorded the comments a full and fair hearing." *Advocates for Highway & Auto Safety v. Fed. Highway Admin.*, 28 F.3d 1288, 1292 (D.C. Cir. 1994). Courts that use this approach have established that an agency can demonstrate open-mindedness by making changes to a final rule in response to public comments, or giving careful consideration to comments submitted in response to a proposed rule. *Air Transp. Ass'n of Am.*, 900 F.2d at 380; see also *Advocates for Highway & Auto Safety*, 28 F.3d at 1292.

Here, the Agencies have not made a "compelling showing" that they kept an open mind at the later stages of the rulemaking process. Most notably, while the Agencies made some changes to the Final Rules based on public comments, those rules were largely "non-substantial technical revisions," 83 Fed. Reg. at 57,567, that Defendants concede "do not alter the fundamental substance of the exemptions set forth in the IFRs." Indeed, the Final Rules and the preambles that accompany them "demonstrate[] a single-minded commitment to the substantive result reached," *Reynolds,* 710 F.3d at 519—to wit, expanding the exemption and accommodation. Because the Agencies' actions indicate closed-mindedness on "the very subject matter about which [they] w[ere] to keep an 'open mind,'" *id.*, the States would likely prevail on their procedural claim even under the more lenient open mind standard.

organization that is not publicly traded to deny contraceptive coverage for its employees for any sincerely held moral conviction.

The APA's substantive requirements command that an administrative rule must be set aside if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C). "It is well settled that an agency may only act within the authority granted to it by statute." *NRDC v. Nat'l Highway Traffic Safety Admin.*, 894 F.3d 95, 108 (2d Cir. 2018). Because "administrative agencies may act only pursuant to authority delegated to them by Congress," an agency must "point to something" in a statute that "gives it the authority" to take the specific action at issue. *Clean Air Council v. Pruitt*, 862 F.3d 1, 9 (D.C. Cir. 2017) (internal quotation marks omitted).

Defendants cite two potential fonts of statutory authority to issue the Final Rules. First, they assert that the ACA includes a broad delegation of authority to the Agencies, permitting them to issue the Final Rules. Second, with specific regard to the Religious Exemption, Defendants assert that RFRA not only authorizes the Agencies to create a religious exemption to the Contraceptive Mandate, but in fact *requires* that the Agencies issue the broad exemption contained within the Final Religious Exemption.

As explained below, both arguments fail. The Final Rules—just as the IFRs before them—exceed the scope of the Agencies' authority under the ACA, and, further, cannot be justified under RFRA. As a result, the Final Rules must be set aside.[20]

### i. The ACA

To reiterate for purposes of clarity, the ACA requires that group health plans and insurance issuers "shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for— . . . with respect to women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by [HRSA]." 42 U.S.C. § 300gg-13(a). It is uncontroverted here that, pursuant to this provision, HRSA has—and by extension the Agencies have—the delegated authority to define what "preventive care" is; that in 2011, HRSA issued guidelines defining "preventive care" to include contraceptives; and that the Final Rules do not purport to remove contraceptives from the coverage mandate. 83 Fed Reg. at 57,537. In light of these provisions, *what* must be provided under the ACA's "preventive care" requirement is clear—all FDA-approved "contraceptive methods, sterilization procedures, and patient education and counseling," 77 Fed. Reg. at 8,725—as is *who* must provide it—any "group health plan" or "health insurance issuer offering group or individual health insurance coverage," 42 U.S.C. § 300gg-13(a).

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[20] Defendants argue that any finding that they lack statutory authority to enact the Final Rules necessarily calls into doubt their ability to enact the 2011 religious exemption, which extended to religious entities such as churches and their auxiliaries. Whatever the merits of that argument, the 2011 religious exemption is not before this Court.

The Agencies, however, contend that the authority to define *what* preventive care will be covered includes a congressional delegation of authority to carve out exceptions to *who* must provide preventive coverage. More specifically, Defendants argue that the Women's Health Amendment necessarily grants them the authority to exempt employers and healthcare plan sponsors from the coverage requirement, based on religious or moral objections to the Mandate. Thus, the precise question at issue is whether the ACA permits the Agencies to develop the exemptions set forth in the Final Rules.

When the scope of the authority delegated to an agency is challenged, that challenge is generally addressed under the analytical framework prescribed by *Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837 (1984). That is because, "[n]o matter how it is framed, the question a court faces when confronted with an agency's interpretation of a statute it administers is always, simply, whether the agency has stayed within the bounds of its statutory authority." *City of Arlington v. FCC*, 569 U.S. 290, 297 (2013) (emphasis removed); see *also Am. Farm Bureau Fed'n v. EPA*, 792 F.3d 281, 295 (3d Cir. 2015) (applying *Chevron* framework to resolve "[w]hether an [agency] interpretation falls within the scope of authority that Congress has delegated") (internal punctuation omitted).

There are two steps to the *Chevron* analysis. Step One asks "whether Congress has directly spoken to the precise question at issue." *Chevron*, 467 U.S. at 842. "If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id.* at 842-43. But, "[i]f the statute is ambiguous on the point," Step Two requires "defer[ence] . . . to the agency's interpretation so long as the construction is 'a reasonable policy choice for the agency to make.'" *National Cable & Telecomm. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 986 (2005) (quoting *Chevron,* 467 U.S. at 845).

Here, as noted, the ACA provides that any "group health plan" or "health insurance issuer offering group or individual insurance coverage *shall*, at a minimum provide coverage for" "preventive care and screenings . . . as provided for in comprehensive guidelines supported by [HRSA]." 42 U.S.C. § 300gg-13(a) (emphasis added). On its face, the Women's Health Amendment does not contemplate exceptions or exemptions to the "preventive care" coverage mandate—much less delegate authority to the Agencies to create such exemptions.[21] Rather, the statute directs that all specified health plans and insurance issuers "shall" cover "preventive care," however defined. "Shall" is a mandatory term that "normally creates an obligation impervious to judicial [or agency] discretion." *Lexecon, Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 35 (1998). Thus, by stating that the specified plans "shall" provide coverage for "preventive care," the statute sets forth who is bound by the coverage mandate (any "group health plan" or "health insur-

[21] As discussed further *infra*, the ACA, in sections outside the Women's Health Amendment, does provide one very specific exception to its broader coverage mandate, for grandfathered health plans. See 42 U.S.C. § 18011. The ACA insurance requirements also do not apply to employers with fewer than 50 employees. See 26 U.S.C. § 4980H(c)(2).

ance issuer offering group or individual insurance coverage"), while delegating to the Agencies the task of defining what counts as "preventive care." The statute further underscores the importance of the Contraceptive Mandate, by stipulating that the specified health plans must provide preventive care coverage "at a minimum" and without "any cost sharing requirements."

Nonetheless, the Agencies assert that they hold the authority to issue the far-reaching exemptions to the Contraceptive Mandate set out in the Final Rules. They argue that the statement "as provided for in comprehensive guidelines supported by [HRSA]" contemplates a broad delegation of authority, that permits the Agencies not only to define preventive care, but also the manner and reach of "preventive care" coverage. 42 U.S.C. § 300gg-13(a). Effectively, the Agencies' argument is that the statute authorizes them to carve out, contrary to the express remits of the statute, categories of entities who need not provide preventive care coverage. But such a grant of authority is inconsistent with the statute's text. Congress has already answered *who* must provide preventive care coverage: any "group health plan" or "health insurance issuer offering group or individual insurance coverage." To permit the Agencies to disrupt this mandate contradicts the plain command of the text.

There are further textual reasons to doubt that the phrase "as provided for in comprehensive guidelines supported by [HRSA]" permits such an extensive delegation. True enough, the statute speaks to "*comprehensive* guidelines," which suggests a broad scope. But the delicate term *support* undermines this contention: it strains credulity to say that by granting HRSA the authority to "support" guidelines on "preventive care," Congress necessarily delegated to HRSA the authority to subvert the "preventive care" coverage mandate through the blanket exemptions set out in the Final Rules.

*MCI Telecommunications Corp. v. American Telephone & Telegraph Co.*, 512 U.S. 218 (1994), is instructive. In that case, the Supreme Court rejected an agency's assertion of authority—similar to the assertion here—to create exceptions to statutory requirements. *Id.* at 234. There, the statutory scheme at issue required that "[e]very common carrier . . . shall . . . file" tariffs, and also granted the Federal Communications Commission ("FCC") the authority to "modify any requirement made by or under the authority of this section." *Id.* at 224 (quoting 47 U.S.C. § 203). The FCC asserted that the grant of authority to "modify" the statutory requirements permitted it to eliminate the filing requirement for certain entities altogether. The Supreme Court firmly rejected this view, finding that the FCC's authority to "modify" statutory requirements did not allow the FCC to make "basic and fundamental changes" to the command of the statute. *Id.* at 225. In a passage particularly on point here, the Supreme Court reasoned that "[i]t is highly unlikely that Congress would leave the determination of whether an industry will be entirely, or even substantially, rate-regulated to agency discretion—and even more unlikely that it would achieve that through such a subtle device as permission to 'modify' rate- filing requirements." *Id.* at 231.

The logic of *M.C.I.* compels the conclusion that Congress's limited delegation to the Agencies does not include authority to create broad exemptions to the Contraceptive Mandate. In *M.C.I.*, the Court held that the agency could not create exceptions for statutorily mandated filing requirements—despite the fact that, there, the text explicitly authorized the agency to "modify" statutory requirements. Here, the statute presents no authority at all to "modify" or waive statutory requirements. As in *M.C.I.*, if Congress intended to grant the Agency such broad authority, it has the means available to it to do so. See *Whitman v. Am. Trucking Ass'n*, 531 U.S. 457, 468 (2001) ("Congress . . . does not . . . hide elephants in mouseholes.").

Defendants argue to the contrary that the text and structure of the ACA permit the Agencies to issue the Final Rules, primarily thanks to the use of the word "as" in the Women's Health Amendment. They note that the Women's Health Amendment follows immediately after—and differs slightly from—another subsection of the ACA that speaks to preventive care coverage, for children. Specifically, the Women's Health Amendment mandates coverage for "preventive care and screenings . . . ***as provided for in*** comprehensive guidelines supported by [HRSA]," while the subsection pertaining to children mandates coverage for "preventive care and screenings ***provided for in the*** comprehensive guidelines supported by [HRSA]." 42 U.S.C. § 300gg-13(a)(3)–(4) (emphasis added). Proceeding from the statutory maxim that statutes "must be interpreted, if possible, to give each word some operative effect," *Walters v. Metro. Educ. Enter., Inc.*, 519 U.S. 202, 209 (1997), Defendants conclude that the inclusion of the word "as" in the women's subsection means that HRSA may determine not only the services covered by the ACA, but also the manner or reach of that coverage.

The impact of the word "as" in this instance can be determined by "look[ing] to dictionary definitions to determine the ordinary meaning of a word," while bearing in mind that "statutory language must be read with reference to its statutory context." *Bonkowski v. Oberg Indus., Inc.*, 787 F.3d 190, 200 (3d Cir. 2015) (internal quotation marks omitted). The term "as" in this context could mean "[u]sed in comparisons to refer to the extent or degree of something," "[u]sed to indicate that something happens during the time when something else is taking place," or "[u]sed to indicate by comparison the way that something happens or is done." *As*, Oxford English Dictionary Online (January 2018), https://en.oxforddictionaries.com/definition/as.

Defendants argue for either the first or third of these definitions, asserting that the "as" here means something like "as you like it." However, the statutory context indicates that the second definition is the most appropriate. When Congress passed the ACA, HRSA had already promulgated guidelines defining children's preventive care. HRSA had not yet promulgated such guidelines for women's preventive care. Thus, the ACA requires coverage "provided for in *the*" preexisting HRSA guidelines for children's care. The use of the article "the" demonstrates that Congress referred to particular, extant guidelines governing children's preventive care. Giving effect to the use of the word "as" with regard to the Women's Health Amendment leads to the conclusion that Congress used "as" here to indicate that the HRSA guidelines would be *forthcoming*, *i.e.* in anticipation of HRSA issuing guidelines—not to the conclusion that the ACA implicitly provides the Agencies with the authority to create exemptions.

Further, even if the word "as" is read to "indicate by comparison" the "extent," "degree" or "way" the Agencies may promulgate guidelines, that definition does not help Defendants, for the following reason. The most natural comparison available in the statute—as Defendants recognize—would be to the pre-ACA children's health preventive services guidelines. And comparing the children's guidelines to the women's guidelines ultimately undermines Defendants' reading of the statute. That is because the children's guidelines simply define a list of "preventive care" services—that is, *what* must be covered. See HHS, *Preventive Care Benefits for Children*, *available at* https://www.healthcare.gov/preventive-care-children. They do not include any exemptions to that coverage; indeed, the children's guidelines do not speak at all to *who* must provide that coverage. And that makes sense because Congress already defined the *who*: any "group health plan" or "health insurance issuer offering group or individual insurance coverage"—the same plans that "shall" cover women's preventive services without cost sharing. Thus if Congress employed "as" here to create a comparison to the children's care guidelines, then Congress assuredly did not intend to permit HRSA to craft exemptions to the types of preventive care that would be required. Rather, Congress intended that HRSA would create a parallel set of guidelines, setting forth the types of "preventive care" to be covered, without exception.

The conclusion that the Women's Health Amendment does not grant HRSA the power to create exemptions is bolstered by other provisions of the ACA. Congress created only a single exemption from the ACA's statutory mandate to cover women's preventive care, for "grandfathered health plans." 42 U.S.C.

§ 18011(e)(3). In accordance with the *expressio unius est exclusio alterius* principle, "[w]hen Congress provides exceptions in a statute . . . [t]he proper inference . . . is that Congress considered the issue of exceptions and, in the end, limited the statute to the ones set forth." *United States v. Johnson*, 529 U.S. 53, 58 (2000). The fact that there is no religious or moral exemption in the explicit text of the statute, while there is an exemption for grandfathered health plans, militates against finding that Congress authorized the Agencies to create any additional exemptions. Indeed, that interpretation is supported by the legislative history, given that, in 2012, Congress explicitly rejected an attempt to add to the ACA an exemption similar to that contained in the Final Rules. See 158 Cong. Rec. S1165 (Mar. 1, 2012); see *also Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 147 (2000) (rejection of an agency's interpretation by Congress is a factor courts consider when determining the meaning of a statute).

For these reasons, the ACA prohibits HRSA from exempting entities from providing such coverage as set forth in the Final Rules. Accordingly, the Final Rules violate the APA and fail at *Chevron*'s Step One.

**ii. RFRA**

Defendants argue that, even if the ACA does not grant the Agencies authority to issue the Final Rules, RFRA independently enables the Agencies to issue the Final Religious Exemption.[22] They assert that the

[22] It should be noted at the outset that Defendants specifically do not propound this argument with respect to the Final Moral Exemption. Nor could they. RFRA protects a person's "exercise of religion," and does not speak to broader moral convictions. 42 U.S.C. § 2000bb-1(a). Thus, because neither the ACA nor RFRA

Contraceptive Mandate cannot be brought into accord with RFRA by anything less that the provisions contained in the Final Religious Exemption, and that, as such, RFRA "required" the promulgation of the rule. But it is the courts, not the Agencies, that determine RFRA's reach. And the Final Religious Exemption goes far beyond RFRA's command.

Congress enacted RFRA in 1993 following the Supreme Court's decision in *Employment Div., Dep't of Human Resources of Ore. v. Smith*, 494 U.S. 872 (1990). In *Smith*, the Supreme Court held that "the Constitution does not require judges to engage in a case-by-case assessment of the religious burdens imposed by facially constitutional laws," and thus strict scrutiny did not apply to Free Exercise challenges to laws of general applicability. *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 424 (2000). Prior to *Smith*, in decisions such as *Sherbert v. Verner*, 374 U.S. 398 (1963), courts employed "a balancing test that took into account whether the challenged action imposed a substantial burden on the practice of religion, and if it did, whether it was needed to serve a compelling government interest," *Hobby Lobby*, 134 S. Ct. at 2760. With RFRA, Congress sought to restore the pre-*Smith* judicial standard. See 42 U.S.C. § 2000bb(b)(1) (stating that a purpose of the statute is "to restore the compelling interest test as set forth in *Sherbert v. Verner*, 374 U.S. 398 (1963) and *Wisconsin v. Yoder*, 406 U.S. 205 (1972) and to guarantee its application in all cases where free exercise of

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grant the Agencies the authority for it, the Final Moral Exemption must be invalidated.

religion is substantially burdened"); see *also Gonzales*, 546 at 424, 430-31.

In accordance with this goal, RFRA provides that the "Government shall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability," unless "it demonstrates that application of the burden to the person-- (1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest." 42 U.S.C. § 2000bb-1(a)-(b). Accordingly, RFRA has two components. First, the government is prohibited from placing a substantial burden on religious exercise. If government action does not impose a substantial burden on religion, then RFRA is not implicated. However, if it does, the government action must be struck down unless it is the least restrictive means of furthering a compelling interest.

Despite Defendants' contention that the Agencies may determine what RFRA demands with respect to the ACA, RFRA provides, to the contrary, that it is the courts that are charged with determining RFRA's application. RFRA "explicitly provides a private cause of action," *Mack v. Warden Loretto FCI*, 839 F.3d 286, 301 (3d Cir. 2016), which permits an aggrieved individual to obtain "Judicial Relief," and contemplates them doing so in a "judicial proceeding," 42 U.S.C. § 2000bb-1(c). More specifically, RFRA states that, "[a] person whose religious exercise has been burdened . . . may assert that violation as a claim or defense in a judicial proceeding and obtain appropriate relief against a government." *Id.* RFRA thus commits to the courts the task of determining whether generally applicable laws violate a person's religious exercise:

"RFRA . . . plainly contemplates that *courts* would recognize exceptions—that is how the law works. RFRA makes clear that it is the obligation of the courts to consider whether exceptions are required under the test set forth by Congress." *Gonzales*, 546 U.S. at 434 (emphasis in original).

Nevertheless, the Agencies contend that they are independently required to assess how RFRA bears on the Contraceptive Mandate and that their authority to promulgate the Final Religious Exemption flows from that obligation. In years past, the Agencies asserted that the accommodation did not impose a substantial burden on any entity's religious exercise and that guaranteeing cost-free contraceptive coverage did serve several compelling government interests. The Agencies now take the obverse positions: that the accommodation constitutes a substantial burden on the religious exercise of objecting employers and that the contraceptive mandate does not serve "any compelling interest." Indeed, they go further—arguing that this new set of views "in itself, is dispositive," as a matter of law. In essence, they have taken on the quintessentially judicial tasks of determining whether the application of the Contraceptive Mandate to objecting entities constitutes a substantial burden, whether any burden was in furtherance of a compelling government interest, and whether the accommodation was the least restrictive means of accomplishing contraceptive coverage. Having taken on those tasks, the Agencies—based on their independent assessments of these legal questions—now claim that RFRA "requires" the Final Religious Exemption.

Their position is unsustainable for a number of reasons, the foremost being that administrative agencies may not simply formulate a view of a law outside their particular area of expertise, issue regulations pursuant to that view, claim that the law requires those regulations, then seek to insulate their legal determination from judicial scrutiny. It is axiomatic that under our constitutional system, "[i]t is emphatically the province and duty of the judicial department to say what the law is." *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 177 (1803). Nothing about RFRA warrants departure from this general maxim. To the contrary, RFRA specifically provides only for "Judicial Relief," 42 U.S.C.A. § 2000bb-1(c), thereby committing interpretative authority to the courts—not to agencies. See *Gonzales*, 546 U.S. at 434; see *also Real Alternatives, Inc. v. Sec'y Dep't of Health & Human Servs.*, 867 F.3d 338, 356 (3d Cir. 2017) ("[I]t is for the reviewing court to determine whether a burden is 'substantial.'"). Indeed, in the *Hobby Lobby* decision, the Supreme Court found that agency action violated RFRA, without ever suggesting that the agency's interpretation was entitled to deference. See *Hobby Lobby*, 134 S. Ct. at 2775-85 (analyzing whether the Contraceptive Mandate violated RFRA, without discussion of deference to agency view); see *also* Thomas W. Merrill, *Step Zero After City of Arlington*, 83 Fordham L. Rev. 753, 759 (2014) ("[T]he [Supreme] Court has never suggested that trans-substantive statutes like the Administrative Procedure Act (APA) or the Religious Freedom Restoration Act (RFRA) should be interpreted by giving deference to agency interpretations.").

Nevertheless, Defendants cast their new legal contentions as reasonable policy decisions within their ambit of expertise. Of course, where a statute leaves gaps for an agency to fill, the agency may change its interpretation so long as it provides a "reasoned explanation for the change." *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016). However, what Defendants attempt to do here is not a change of interpretation regarding an ambiguous statute they are tasked with administering. Rather, Defendants are baldly asserting—with respect to a statute that does not explicitly delegate them any authority—what RFRA "requires." Defendants have no expertise in administering RFRA. See *Gonzales*, 546 U.S. at 434; see *also Real Alternatives*, 867 F.3d at 356; *Iglesia Pentecostal Casa De Dios Para Las Naciones, Inc. v. Duke*, 718 F. App'x 646, 653 (10th Cir. 2017) (holding that the question of whether a RFRA violation exists is "a legal determination that Congress has not exclusively entrusted to" agencies) (internal quotation marks omitted). While Defendants may change course in their legal assessment of what RFRA commands, this is not the final word. Ultimately, it is up to the courts to decide.

It is true, as Defendants point out, that there is a great deal of "legal uncertainty" about RFRA's precise application to the Contraceptive Mandate. But on the specific question presented here—whether RFRA "requires" the Final Religious Exemption—the law is clear.

To set out Defendants' position in greater detail, yet another review of *Hobby Lobby* is in order. There, the Supreme Court held that "[t]he contraceptive mandate, as applied to closely held corporations, violates RFRA." 134 S. Ct. at 2785. The Supreme Court reasoned that the Contraceptive Mandate imposed a substantial burden on the religious exercise of the plaintiffs—closely held corporations—and that the burden was not the least restrictive means of providing contraceptive coverage to women. With specific regard to the least restrictive means element, the Supreme Court explained that the Agencies had already created a less restrictive means to both ensure women had contraceptive coverage and reduce the burden on religious objectors: the accommodation. *Id.* at 2781-82. As noted, the accommodation allowed eligible religious objectors to notify their healthcare administrator of their religious objection, and the administrator would then have to provide the legally required contraceptive services directly to women covered under the employer's plan. Because the accommodation "[did] not impinge on the plaintiffs' religious belief that providing insurance coverage for the contraceptives at issue here violates their religion," and still accomplished the government's goal of providing contraceptive coverage, the Supreme Court found that the Contraceptive Mandate, as applied to the plaintiffs, was not the least restrictive means, and thus violated RFRA. *Id.* at 2782. Importantly, the Supreme Court reserved on the question of "whether an approach of this type complies with RFRA for purposes of all religious claims." *Id.* Following *Hobby Lobby*, in *Zubik*, the Supreme Court declined to decide the question of whether the accommodation itself imposed a substantial burden on plaintiff nonprofits' religious exercise; instead, it remanded so that the parties might come to a resolution on their own, whereby the plaintiffs' employees could receive contraceptive coverage without the plaintiffs' having to submit the form required by the accommodation. 136 S. Ct. at 1559-60.

Based on these rulings, Defendants assert that RFRA "requires" the Religious Exemption, because their previous attempts to satisfy RFRA with the accommodation failed. This theory rests on three legal conclusions: (1) a blanket exemption from the Contraceptive Mandate for religious objectors strays no further than RFRA demands; (2) the accommodation did not relieve the substantial burden identified by the Supreme Court in *Hobby Lobby*; and, (3) the contraceptive mandate imposes a substantial burden on publicly traded corporations. But each of these views is either incorrect under the law—as previously determined by precedential rulings—or a significant extension of existing doctrine. Accordingly, Defendants have stepped beyond the demands of RFRA, and the Final Religious Exemption cannot be justified as a "requirement" of RFRA.

As to the first conclusion—that a blanket exemption for religious objectors goes no further than RFRA demands—a close read of *Hobby Lobby* demonstrates that the Agencies' conclusion is incorrect. There, the Supreme Court explained that an exemption akin to the Final Religious Exemption goes beyond RFRA's requirements. 134 S. Ct. at 2775 n.30. More specifically, prior to enacting the ACA, Congress had considered but ultimately voted down a 'conscience amendment,' which, like the Final Religious Exemption, enabled an employer or insurance provider to deny coverage based on its asserted religious beliefs. *Id.* The *Hobby Lobby* majority concluded it was "reasonable to believe that" Congress rejected the amendment because such a "blanket exemption" for religious objectors "extended more broadly than the . . . protections of RFRA." *Id.* That is because "it would not have subjected religious-based objections to the judicial scrutiny called for by RFRA, in which a court must consider not only the burden of a requirement on religious adherents, but also the government's interest and how narrowly tailored the requirement is." *Id.* Thus, as the *Hobby Lobby* Court recognized, the blanket exemption the Agencies have set forth "extend[s] more broadly than the . . . protections of RFRA." Plainly then, RFRA cannot "require" such a rule, which creates precisely this blanket exemption.

As to the second conclusion—that the accommodation imposes a substantial burden on the religious exercise of objecting entities—Defendants are incorrect under the law of this circuit. While the Supreme Court has not resolved this precise issue, Third Circuit authority demonstrates that, contrary to the Agencies' view, the accommodation does *not* impose a substantial burden. See *Geneva Coll. v. Sec'y U.S. Dep't of Health & Human Servs.*, 778 F.3d 422, 442 (3d Cir. 2015), *vacated and remanded sub nom. Zubik v. Burwell*, 136 S. Ct. 1557 (2016) (per curiam); see *also Real Alternatives*, 867 F.3d at 356 n.18. The accommodation has been specifically upheld against a RFRA challenge by the Third Circuit, first, and directly, in *Geneva Coll.*, 778 F.3d at 442, and second, by implication, in *Real Alternatives*, 867 F.3d at 356 n.18. Defendants argue that *Geneva* is no longer good law because it was vacated by the Supreme Court in *Zubik*. But the Supreme Court in *Zubik* specifically declined to decide the merits of the RFRA challenge to the accommodation, by explicitly refraining from "decid[ing] whether petitioners' religious exercise has been substantially burdened." 136 S. Ct. at 1560. Instead, the Supreme Court vacated *Geneva* (and related decisions from other Circuit courts) and remanded for the express purpose of allowing the parties "an opportunity to arrive at an approach going forward that accommodates petitioners' religious exercise while at the same time ensuring that women covered by petitioners' health plans receive full and equal health coverage, including contraceptive coverage." *Id.*

Following *Zubik*, the Third Circuit reiterated in *Real Alternatives* that it "continue[s] to believe . . . that the regulation at issue"—the accommodation—"did not impose a substantial burden." *Real Alternatives*, 867 F.3d at 356 n.18. Defendants characterize this statement as dicta, and indeed, the issues in the two cases were slightly distinct. In *Geneva*, nonprofits eligible for the accommodation asserted that filling out the accommodation form "facilitated" or "triggered" the provision of contraceptives, thereby substantially burdening their religious exercise. 778 F.3d at 427. In *Real Alternatives*, employees of a secular employer similarly asserted that the Contraceptive Mandate violated RFRA because their purchase of insurance enabled the provision of contraceptives. 867 F.3d at 359. What Defendants overlook is that in *Real Alternatives* the Third Circuit reaffirmed and reapplied the reasoning of *Geneva*. In both cases, the Third Circuit found that there was no substantial burden on the plaintiffs' religious exercise because their actions were insufficiently related to the provision of contraceptives and "an independent obligation on a third party can[not] impose a substantial burden on the exercise of religion in violation of RFRA." *Id.* at 364 (quoting *Geneva*, 778 F.3d at 440-41). Accordingly, applying the law of this circuit as announced in *Real Alternatives*, the accommodation does not impose a substantial burden on religious exercise.

The third conclusion—that the Contraceptive Mandate imposes a substantial burden on the religious exercise of publicly traded corporations—goes considerably beyond existing jurisprudence. In *Hobby Lobby*, the Supreme Court found that the Contraceptive Mandate imposed a substantial burden on the specific plaintiffs in that case: "closely held corporations, each owned and controlled by members of a single family." 134 S. Ct. at 2774. It explicitly declined to extend its holding to publicly traded corporations, suggesting that publicly traded corporations would be unlikely to hold a singular, sincere religious belief:

> These cases, however, do not involve publicly traded corporations, and it seems unlikely that the sort of corporate giants to which HHS refers will often assert RFRA claims. HHS has not pointed to any example of a publicly traded corporation asserting RFRA rights, and numerous practical restraints would likely prevent that from occurring. For example, the idea that unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run a corporation under the same religious beliefs seems improbable. In any event, we have no occasion in these cases to consider RFRA's applicability to such companies.

*Id.* Defendants assert that it is reasonable to include publicly traded corporations in the Religious Exemption. But, as *Hobby Lobby* makes clear, RFRA does not "require" this expansion.

Thus, even if the Agencies are correct that the accommodation imposes a substantial burden on religious employers, and that they must act, through regulation, to relieve that burden,[23] the Final Religious

[23] Defendants contend that the Final Rules—like earlier rules that created the exemption and accommodation framework—are merely the Agencies' attempts to respond to the Supreme Court's decisions in *Hobby Lobby*, *Wheaton College*, and *Zubik*. After each of those decisions, the Agencies promulgated generally applicable regulations that expanded or modified the exemption and accommodation framework in an attempt to bring the Agencies' actions in line with what the Supreme Court said RFRA commands. According to Defendants, that is all that is happening here, the only difference being the States have now challenged the Agencies' authority to do so.

Fair enough. Nonetheless, this challenge raises a fundamental question: whether RFRA grants agencies independent authority to issue regulations of general applicability, like the Final Religious Exemption. It is worth noting that the scope of affirmative authority, if any, that RFRA grants to agencies to issue regulations of general applicability— whether in response to judicial interpretations of RFRA or based on their own assessments of RFRA's application— is distinctly undetermined. Neither *Hobby Lobby*, nor *Wheaton College*, nor *Zubik* resolved this question—nor, does it appear, has any other court. The statutory language does not provide a clear answer. On the one hand, RFRA "applies to all Federal law, *and the implementation of that law*, whether statutory or otherwise," which could possibly be read to grant agencies some authority to promulgate regulations on a generalized basis. 42 U.S.C. § 2000bb-3(a) (emphasis added). However, RFRA is fundamentally a remedial measure, that by its terms "provide[s] a claim or defense to persons whose religious exercise is substantially burdened by government," *id.* at § 2000bb(b)(2), in a "*judicial proceeding*" in order to "obtain appropriate relief against a government," *id.* at § 2000bb-1(c) (emphasis added). See also *Hobby Lobby*, 134 S. Ct. at 2775 n.30; *Gonzales*, 546 U.S. at 430-31, 434. Indeed, quite recently, the federal government suggested that RFRA does not permit an agency to create exemptions to regulations absent a judicial determination, albeit in a case that did not focus on this issue in great depth. See *Iglesia Pentecostal*, 718 F. App'x at 653 (recounting federal government's position that "[a]bsent a judicial finding that the regulation violates

Exemption sweeps further than RFRA would require. The Agencies' willingness to exceed the bounds of existing case law demonstrates that the Agencies have cast aside RFRA's mandate for "judicial scrutiny . . . in which a *court* must consider not only the burden of a requirement on religious adherents, but also the government's interest and how narrowly tailored the requirement is." *Id.* at 2775 n.30 (emphasis added). Accordingly, the Religious Exemption cannot be justified under RFRA.

Because neither the ACA nor RFRA confer authority on the Agencies to promulgate the Religious Exemption, the rule is invalid.[24]

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RFRA, neither the director of USCIS nor the AAO has any discretion to set aside any provision of those regulations.") (brackets omitted).

Put simply, it is not clear what, if any, affirmative authority RFRA grants to agencies to issue regulations of general applicability. The parties do not point to any authority that resolves this question. Nor has independent research yielded definitive answers. While this large question looms in the background, the Court need not decide it here. Whatever the extent of an agency's authority under RFRA, the Agencies here have exceeded it in promulgating the Final Religious Exemption.

[24] Given its holding that Defendants violated the procedural and substantive provisions of the APA in issuing the Final Rules, and in view of the admonition that "courts should be extremely careful not to issue unnecessary constitutional rulings," *American Foreign Serv. Ass'n v. Garfinkel*, 490 U.S. 153, 161 (1989) (per curiam), it is unnecessary to proceed to the constitutional issues. Similarly, because the Final Rules violate the substantive provisions of the APA for the reasons given, there is no need to reach the States' other statutory challenges to the Final Rules.

In light of these conclusions, the States have demonstrated an adequate likelihood of success on the merits in support of their motion for preliminary relief.

### 3. Irreparable Harm

The second factor to consider in deciding the States' motion is whether they have demonstrated that they are likely to suffer irreparable harm in the absence of a preliminary injunction. The Supreme Court's "frequently reiterated standard requires plaintiffs seeking preliminary relief to demonstrate that irreparable injury is *likely* in the absence of an injunction." *Winter*, 555 U.S. at 22 (emphasis in original); see *id.* ("Issuing a preliminary injunction based only on a possibility of irreparable harm is inconsistent with the characterization of injunctive relief as an extraordinary remedy that may be awarded only upon a clear showing that the plaintiff is entitled to such relief."). The States assert that they will suffer two forms of irreparable harm in the absence of an injunction: (1) significant damage to the States' fiscal integrity; and (2) harm to the health, safety, and wellness of the women of Pennsylvania and New Jersey. The Court finds both sufficient to justify preliminary relief.

As to the harm to the States' fiscal integrity, the States' evidence demonstrates that it is likely that the Final Rules will cause direct and irreparable harm. The States will become obligated to shoulder much of the burden of providing contraceptive services to women who lose contraceptive care because their health plans take advantage of the expanded exemptions contained in the Final Rules. See Steinberg Decl. ¶¶ 27-29 (discussing Pennsylvania); Geenace Decl. ¶¶ 15-17 (discussing New Jersey). Such women will seek contraceptive services elsewhere and, as Defendants noted in issuing the IFRs, may turn to "multiple . . . State[] and local programs that provide free or subsidized contraceptives for low-income women" for alternative coverage. See 82 Fed. Reg. at 47,803. In Pennsylvania, these state funded programs include: Medicaid, called "Medical Assistance;" the Family Planning Service Program; and the Commonwealth's network of clinics funded under the Title X grant program. See Allen Decl. ¶¶ 3-18; Steinberg Decl. ¶ 16. New Jersey funds similar programs through Medicaid, known as "NJ Family Care," and the State's Plan First Program. Adelman Dec. ¶¶ 9-14. As women in the States lose contraceptive coverage through their health insurance plans and turn to state-funded programs, it is likely that the States will bear the added financial burden occasioned by the increase in women who need contraceptive care coverage. See Mendelsohn Decl. ¶¶ 15-18; Allen Decl. ¶ 23; Geenace Decl. ¶¶ 15-18.

The States' harm is not merely speculative; it is actual and imminent. The Final Rules estimate that at least 70,500 women will lose coverage. See 83 Fed. Reg. at 57,578.[25] Thus, the only serious disagreement is not whether the States will be harmed, but *how much*. Though Defendants argue that the States have not identified any individual who has lost coverage already, there is no need to wait for the axe to fall before an injunction is appropriate, particularly where Defendants have estimated that it is about to fall on thousands of women—and, as a corollary, on the

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[25] The States argue that there is reason to believe the number is significantly higher because organizations taking advantage of the exemption need not inform the Agencies of their plan to do so.

States. See *Texas*, 809 F.3d at 186 (granting relief based on predicted harm to States' fiscs).

While "loss of money" is generally insufficient to merit a preliminary injunction, see *Instant Air Freight Co. v. C.F. Air Freight, Inc*., 882 F.2d 797, 801 (3d Cir. 1989), here, the harm to the States' fiscs is irreparable because they will not be able to recover any economic damages that result from the Final Rules. That is because a party—like the States here—which alleges an APA violation may not recover monetary damages from the federal government on that claim. See 5 U.S.C. § 702 (permitting relief "other than money damages"); *California*, 911 F.3d at 581 (finding irreparable harm in APA case on similar grounds). Therefore, if the Final Rules are ultimately struck down as violative of the APA, the States will not be able to recoup any money they expend on contraceptive care in the interim. In such circumstances, a preliminary injunction is appropriate. See*, e.g., N.J. Retail Merchants Ass'n v. Sidamon-Eristoff*, 669 F.3d 374, 388 (3d Cir. 2012) (holding that a preliminary injunction is appropriate where a movant could not recover damages from a State due to sovereign immunity).

In addition to pecuniary harm, the States also stand to suffer injury to their interest in protecting the safety and well-being of their citizens. See *Alfred L. Snapp*, 458 U.S. at 607 (observing that a State has a "quasi-sovereign interest in the health and wellbeing—both physical and economic—of its residents in general"). The States' witnesses explained that employers taking advantage of the Final Rules will result in more women losing no-cost contraceptive coverage. Mendelsohn Decl. ¶¶ 14-15; Adelman Decl. ¶ 20. As a result, women will likely forgo contraceptive services or seek out less expensive and less effective types of contraceptive services in the absence of no-cost insurance coverage. Weisman Decl. ¶¶ 45-48; Chuang Decl. ¶¶ 36-39; see *also* Adam Sonfield, *What is at Stake with the Federal Contraceptive Coverage Guarantee?*, 20 Guttmacher Policy Review 8, 9 (2017) (reporting that women cite cost as a significant factor in determining whether to purchase contraceptive services and which contraceptive services to use). Disruptions in contraceptive coverage will lead to women suffering unintended pregnancies and other medical consequences. Butts Decl. ¶¶ 57-59; Institute of Medicine, *Clinical Prevention Services* at 107 (explaining that contraceptive services are used to treat menstrual disorders, acne, hirsutism, and pelvic pain, in addition to assisting family planning and birth spacing).[26] The negative effects of even a short period of decreased access to no-cost contraceptive services are irreversible.

The States have therefore showed that they are likely to suffer irreparable harm as a result of the Rules' impact on both the States' fiscs and the welfare of the States' citizens.

**4. Balance of the Equities**

The third factor is that the balance of the equities tips in favor of granting a preliminary injunction. "Balancing the equities" is jurisprudential "jargon for choosing between conflicting public interests." *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579,

[26] Increased unplanned pregnancies will also inflict additional pecuniary harm on the States. See Steinberg Decl., ¶ 30 (discussing study finding that 68% of unplanned births are paid for by public insurance programs, compared to only 38% of planned births).

609 (1943) (Frankfurter, J., concurring). Here, Congress has already struck the balance: the Women's Health Amendment was intended to ensure women received no-cost coverage for preventive services, which includes contraceptives. As lead sponsor of the Women's Health Amendment, Senator Barbara Mikulski, explained: the amendment "leaves the decision of which preventive services a patient will use between the doctor and the patient." 155 Cong. Rec. S11988 (Nov. 30, 2009) (statement of Sen. Barbara Mikulski). Congress enacted the Women's Health Amendment to guarantee that "the decision about what is medically appropriate and medically necessary is between a woman and her doctor." *Id.* Where "Congress itself has struck the balance, [and] has defined the weight to be given the competing interests, a court of equity is not justified in ignoring that pronouncement under the guise of exercising equitable discretion." *Youngstown Sheet*, 343 U.S. at 609-10.

Here, given the States' clear interest in securing the health and well-being of women residents and limiting their costs for contraceptive services, the balance of the equities weighs in their favor. Defendants will not be substantially prejudiced by a preliminary injunction. If the Final Rules were issued in violation of applicable law, they will have suffered no harm. If Defendants ultimately prevail, then a preliminary injunction will have merely delayed their preferred regulatory outcome.

**5. Public Interest**

"If a plaintiff proves both a likelihood of success on the merits and irreparable injury, it almost always will be the case that the public interests favors preliminary relief." *Issa v. Sch. Dist. of Lancaster*, 847 F.3d

121, 143 (3d Cir. 2017) (internal quotation marks omitted). So it proves here. A preliminary injunction is unquestionably in the public interest because it maintains the status quo pending the outcome of this litigation. The Final Rules permit any entity to opt out of coverage after 30 to 60 days' notice to plan members. This litigation will not conclude in that short span. A preliminary injunction will maintain the status quo: those eligible for exemptions or accommodations prior to October 6, 2017 will maintain their status; those with injunctions preventing enforcement of the Contraceptive Mandate will maintain their injunctions;[27] those alleging RFRA violations may pursue "Judicial Relief;" and those with coverage will maintain their coverage as well.

**D. Remedy**

Before concluding, an additional word is required on the scope of the preliminary injunction to be issued. When the IFRs were initially before this Court, they were enjoined generally, without any specific geographic or temporal limitation. See *Pennsylvania*, 281 F. Supp.3d at 585.

Since then, however, much has been made about the propriety (or impropriety) of so- called nation-wide injunctions. See*, e.g.*, *Trump v. Hawaii*, 138 S. Ct. 2392, 2425 (2018) (Thomas, J., concurring); Zayn Siddique, *Nationwide Injunctions*, 117 Colum. L. Rev. 2095 (2017); Samuel L. Bray, *Multiple Chancellors:*

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[27] For example, Defendant-Intervenor has secured a permanent injunction, preventing enforcement of the Contraceptive Mandate against it. See *Little Sisters of the Poor v. Azar*, No. 1:13-cv-02611, Dkt. 82 (D. Colo. May 29, 2018). Nothing in this Court's ruling will disturb that order.

*Reforming the National Injunction*, 131 Harv. L. Rev. 417 (2017). In light of this increased focus on the proper exercise of district courts' remedial powers, it is prudent to explain in some detail why a nation-wide injunction is appropriate here.

First, it is well established that a district court sitting in equity has the *authority* to enter a nation-wide injunction. See *Leman v. Krentler-Arnold Hinge Last Co.*, 284 U.S. 448, 451 (1932) (holding district court's order "binding upon the respondent, not simply within the District of Massachusetts, but throughout the United States"); *Texas*, 809 F.3d at 188 ("[T]he Constitution vests the District Court with 'the judicial power of the United States.' That power is not limited to the district wherein the court sits but extends across the country.") (quoting U.S. Const. art. III, § 1); *McLendon v. Cont'l Can Co.*, 908 F.2d 1171, 1182 (3d Cir. 1990) (holding "[f]ull relief required a nationwide injunction"). The issue, then, is whether a nation-wide injunction is appropriate here, given the facts of this specific case.

"In shaping equity decrees, the trial court is vested with broad discretionary power." *Lemon v. Kurtzman*, 411 U.S. 192, 200 (1973) (plurality opinion). That is because crafting equitable remedies is an inexact science; instead, "equitable remedies are a special blend of what is necessary, what is fair, and what is workable." *Id.*; see *also Trump v. Int'l Refugee Assistance Project*, 137 S. Ct. 2080, 2087 (2017) ("Crafting a preliminary injunction is an exercise of discretion and judgment, often dependent as much on the equities of a given case as the substance of the legal issues it presents."). As Justice Douglas succinctly put it seventy-five years ago: "[t]he essence of equity jurisdiction has been the power of the Chancellor to do equity and to mould each decree to the necessities of the particular case. Flexibility rather than rigidity has distinguished it." *Hecht Co. v. Bowles*, 321 U.S. 321, 329 (1944).

The Supreme Court articulated the relevant standard for determining the proper scope of a preliminary injunction in *Califano v. Yamasaki*, 442 U.S. 682 (1979), stating that "injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs." *Id.* at 702 (emphasis added). Subsequent Supreme Court and lower court decisions have treated the "no more burdensome than necessary" rubric as the "general rule" for determining whether an injunction is overbroad. *Madsen v. Women's Health Center, Inc.*, 512 U.S. 753, 765 (1994); s*ee also Trump*, 137 S. Ct. at 2090 (Thomas, J., concurring in part and dissenting in part); s*ee also McLendon*, 908 F.2d at 1182 ("In granting injunctive relief, the court's remedy should be no broader than necessary to provide full relief to the aggrieved plaintiff.").[28]

The *Califano* standard requires district courts to balance the competing principles of providing complete relief to meritorious plaintiffs against a defendant's right to be free from overly burdensome injunctions. The complete relief requirement reflects the "well-settled principle that the nature and scope of the remedy are to be determined by the violation." *Milliken v. Bradley*, 433 U.S. 267, 281-82 (1977). Where a

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[28] In *Califano*, the Court indicated that the "no more burdensome than necessary" standard is a general rule of injunctions, regardless of whether a nation-wide class-action is certified. *See* 442 U.S. at 702.

violation has been found, "the remedy does not 'exceed' the violation if the remedy is tailored to cure the 'condition that offends [the law.]'" *Id.* at 282 (quoting *Milliken v. Bradley*, 418 U.S. 717, 738 (1974)).

The complete relief principle explains why, in APA cases, "when a reviewing court determines that agency regulations are unlawful, the *ordinary result* is that the rules are vacated—not that their application to the individual petitioners is proscribed." *Nat'l Min. Ass'n v. U.S. Army Corps of Eng'rs,* 145 F.3d 1399, 1409 (D.C. Cir. 1998) (internal quotation marks omitted and emphasis added). Where "agency action . . . consist[s] of a rule of broad applicability" that violates the strictures of the APA, *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 913 (Blackmun, J., dissenting),[29] a remedy "tailored to cure the condition that offends [the law]" may be correspondingly broad, *Milliken*, 433 U.S at 282 (internal quotation marks omitted). Thus, when an individual challenges agency action and prevails, "the result is that the rule is invalidated, not simply that the court forbids its application to a particular individual." *Lujan*, 497 U.S. at 913 (Blackmun, J., dissenting).[30] Put differently, the national character of an

[29] In *Nat'l Min. Ass'n*, the D.C. Circuit explained that, while Justice Blackmun's observations came in a dissent, they "apparently express[ed] the view of all nine Justices on this question." 145 F.3d at 1409.

[30] Indeed, at least one scholar has argued that the language of the APA—providing that a reviewing court "shall . . . hold unlawful and set aside" agency action that is arbitrary or capricious, 5 U.S.C. § 706—requires courts to vacate all unlawful agency actions. See Brian S. Prestes, *Remanding Without Vacating Agency Action*, 32 Seton Hall L. Rev. 108, 110 (2001).

APA violation "ordinar[ily]" demands a national remedy. *Nat'l Min. Ass'n*, 145 F.3d at 1409.

At the same time, the Supreme Court has warned that injunctions should be "no more burdensome to the defendants than necessary." *Califano*, 442 U.S. at 702. Over fifty years ago, Justice Fortas cautioned:

> [A]rming each of the federal district judges in this Nation with power to enjoin enforcement of regulations and actions under the federal law designed to protect the people of this Nation. . . is a general hunting license; and I respectfully submit, a license for mischief because it authorizes aggression which is richly rewarded by delay in the subjection of private interests to programs which Congress believes to be required in the public interest.

*Toilet Goods Ass'n v. Gardner*, 387 U.S. 167, 183 (1967) (Fortas, J., dissenting). More recently, the Supreme Court has warned that overbroad injunctions "have detrimental effect[s] by foreclosing adjudication by a number of different courts and judges," which "often will be preferable in order to gain the benefit of adjudication by different courts in different factual contexts." *Califano*, 442 U.S. at 701-02; *California*, 911 F.3d at 583 (raising same concern). In addition, courts worry that overly broad injunctions invite "forum shopping, which hinders the equitable administration of laws." *California*, 911 F.3d at 583 (citing Bray, *Multiple Chancellors*, 131 Harv. L. Rev. at 458-59).

The concerns about overbroad injunctions carry into APA cases. Courts have, at times, resisted granting nation-wide relief, even where "agency action . . . consist[s] of a rule of broad applicability." *Lujan*, 497

U.S. at 913 (Blackmun, J., dissenting); see*, e.g.*, *California*, 911 F.3d at 584 (finding an APA violation, but concluding "the scope of the preliminary injunction is overbroad"); *Baeder v. Heckler*, 768 F.2d 547, 553 (3d Cir. 1985) (holding regulation invalid, but determining district court did not have "the authority to issue an injunction aimed at controlling [Agency's] behavior in every . . . case in the country"). Thus, while an APA violation may "ordinar[ily]" result in a nation-wide remedy, the potential dangers of an overbroad injunction must still be weighed when crafting a remedy for an APA violation.

The upshot is that striking the appropriate balance between providing complete relief to meritorious plaintiffs, on the one hand, and protecting defendants from overly burdensome injunctions, on the other, is necessarily a difficult line-drawing exercise, even in APA cases.

To see why, recall the injury the States stand to suffer from enforcement of the Final Rules: both Pennsylvania and New Jersey complain that, because enforcement of the Final Rules will result in "numerous insureds—and their female dependents—[losing] the medical coverage for contraceptive care required by the Affordable Care Act," the States will suffer "significant, direct and proprietary harm" in the form of increased use of state-funded contraceptive services as well as increased costs associated with unintended pregnancies. Affording complete relief to the States would require the Court to enjoin enforcement of the

Final Rules as to all entities that "offer[] and arrange[]" health insurance to insureds residing in Pennsylvania or New Jersey.[31]

But drafting—much less enforcing—a preliminary injunction that runs only to those entities is nigh impossible. Neither the Court nor the parties can readily ascertain what those entities are or whether they intend to take advantage of the exemption, given that providing notice to the Agencies is only optional under the Final Rules. At the same time, the Court cannot, consistent with Rule 65 of the Federal Rules of Civil Procedure simply and broadly enjoin "all entities that offer and arrange health insurance to insureds residing in Pennsylvania or New Jersey." That is because "[e]very order granting an injunction . . . must . . . state its terms specifically and describe in reasonable detail—and not by referring to the complaint or other document—the act or acts restrained." Fed. R. Civ. P. 65 (internal punctuation omitted).

Given the challenges associated with crafting a "perfect" injunction, district courts tend to rely on geographic proxies when tailoring a remedy. For example, the Ninth Circuit—hearing an appeal from a district court decision that also enjoined the enforcement of the IFRs nation- wide—held that "an injunction that

[31] Even that may not provide complete relief because a non-resident that lost contraceptive coverage may try to take advantage of the States' programs. *Cf. Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2304 (2016) (explaining that, following the enactment of a Texas regulation that would force the closure of abortion clinics in west Texas, "the Court of Appeals said that women in El Paso wishing to have an abortion could use abortion providers in nearby New Mexico").

applies only to the plaintiff states would provide complete relief to them." *California*, 911 F.3d at 584; see *also California v. Health & Human Servs.*, — F. Supp. —, No. 17-cv-5783, ECF No. 234 (N.D. Cal. 2019) (enjoining enforcement of Final Rules within plaintiff States only). Defendants similarly argue that, if the Final Rules are to be enjoined, then the injunction should be limited to Pennsylvania and New Jersey.

The problem with the Ninth Circuit's approach, however, is that it simply does not afford the meritorious plaintiffs—the States—complete relief. Hundreds of thousands of the States' citizens travel across state lines—to New York, Ohio, Delaware, Maryland, West Virginia and even further afield—to work for out-of-state entities. See Amici Curiae Brief of Massachusetts, *et al.* in Support of Plaintiffs' Motion for a Preliminary Injunction, at 13-14 (2019) (noting that "548,040 New Jersey residents, or 14% of the workforce, and 299,970 Pennsylvania residents, or 5.4% of the workforce" travel to jobs in other states) (citing U.S. Census Bureau, *Out-of-State and Long Commutes: 2011, American Community Survey Reports*, at 10 (Feb. 2013), *available at* https://www2.census.gov/library/publications/2013/acs/acs-20.pdf). Furthermore, with their many universities and educational institutes, the States take in tens of thousands of out-of-state students each year. *Id.* at 14 (noting that Pennsylvania takes in 32,000 out-of-state students alone) (citing Nat'l Ctr. for Education Statistics, *Residence and Migration of All First-Time Degree/Certificate-*See*king Undergraduates* (2017), *available at* https://nces.ed.gov/programs/digest/d17/tables/dt17_309.20.asp?current=ye).

An injunction limited to Pennsylvania and New Jersey would, by its terms, not reach Pennsylvania and New Jersey citizens who work for out-of-state employers. Despite residing in the States, those out-of-state workers could lose contraceptive coverage if the out-of-state employers took advantage of the exemptions included in the Final Rules, resulting in proprietary harm to the States. Nor would an injunction limited to the States cover out-of-state students attending school in Pennsylvania and New Jersey, who may not be considered "residents" of the States. Such students, by remaining on their parents' out-of-state employer-based health plans or other health insurance through their State of "residency," could lose contraceptive coverage but still turn to in-state publicly-funded clinics for contraceptive coverage. Put differently, "an injunction that applies only to the plaintiff states" *would not* "provide complete relief to them" because it *would not* "prevent the economic harm extensively detailed in the record." *California*, 911 F.3d at 584.

Injunctions that are intermediate in geographic scope—that is, applicable beyond the States but not nation-wide—encounter the same problems in ensuring "complete relief to the plaintiffs." *Madsen*, 512 U.S. at 765. An injunction limited to the Third Circuit, for example, would fail to account for the thousands of Pennsylvania and New Jersey citizens that commute to neighboring or nearby states outside the Third Circuit for work. Similarly, an injunction covering the surrounding states would not account for the fact that the States draw out-of-state students from across the nation.

At the same time, the Court recognizes that, on the record before it, a nation-wide injunction may prove "broader than necessary to provide full relief" to the States. *McLendon*, 908 F.2d at 1182. The States concede, for example, that there is no evidence that any citizen of the States physically commutes to New Mexico, so an injunction that covers the Land of Enchantment appears "broader than unnecessary." Nor have the States presented evidence of a New Mexican that currently attends a Pennsylvania or New Jersey institute of higher learning, who may lose her contraceptive coverage through her out-of-state insurance. The same can be said for a host of other states.

Ultimately, crafting a remedy that provides "complete relief to the plaintiffs," while being "no more burdensome to the defendant than necessary" would require empirical data—the working conditions of each and every citizen of the States—that is simply not ascertainable.[32] In the absence of such information, the Court must exercise "discretion and judgment," *Trump*, 137 S. Ct. at 2087, in balancing the competing risks and uncertainties associated with either a potentially under- or over-inclusive remedy, bearing in mind the maxim that "[w]e should not allow the infeasible perfect to oust the feasible good." *Resorts Int'l Hotel Casino v. NLRB*, 996 F.2d 1553, 1558 (3d Cir. 1993) (internal quotation marks and alternations omitted).

On balance, the Court finds that, in this case, potential over-inclusiveness is the more prudent route. For one, anything short of a nation-wide injunction would likely fail to provide the States "complete relief."

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[32] This is neither an explicit or implicit critique of the parties. Rather, it is the frank observation that crafting a perfect remedy would require information that would be insurmountable to gather and maintain.

*Cf. Texas*, 809 F.3d at 188 ("[T]here is a substantial likelihood that a geographically-limited injunction would be ineffective because DAPA beneficiaries would be free to move among states," which would leave Texas open to potential injury); see *also* Siddique, *Nationwide Injunctions*, 117 Colum. L. Rev. at 2146-47 ("If one agrees with the district court that Texas suffers some injury from having deferred action beneficiaries within its territorial boundaries, the only way to afford *complete* relief to Texas and prevent any deferred action beneficiaries from making their way to Texas is by enjoining the grant of deferred action nationwide."). While a nation-wide injunction may prove overbroad, there is no more geographically limited injunction that protects the States from potential harm.

Second, it is far from clear how burdensome a nation-wide injunction would be on Defendants, given that when "agency regulations are unlawful, the ordinary result is that the rules are vacated—not that their application to the individual petitioners is proscribed." *Nat'l Min. Ass'n,* 145 F.3d at 1409.

Third, one of the risks associated with a nationwide injunction—namely, "foreclosing adjudication by a number of different courts," *Califano*, 442 U.S. at 701-02—is not necessarily present here, as the parallel litigation in the Ninth Circuit evidences. See *also* Spencer E. Amdur & David Hausman, *Nationwide Injunctions and Nationwide Harm*, 131 Harv. L. Rev. F. 49, 53 n.27 (2017) (noting that "in practice, nationwide injunctions do not always foreclose percolation," and giving several recent examples).

Fundamentally, given the harm to the States should the Final Rules be enforced—numerous citizens losing contraceptive coverage, resulting in "significant, direct and proprietary harm" to the States in the form of increased use of state-funded contraceptive services, as well as increased costs associated with unintended pregnancies—a nation-wide injunction is required to ensure complete relief to the States.

An appropriate order follows.

January 14, 2019 BY THE COURT:

/s/Wendy Beetlestone, J.
WENDY BEETLESTONE, J.

**APPENDIX D**

**IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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| COMMONWEALTH OF PENNSYLVANIA,<br>Plaintiff,<br>v.<br>DONALD J. TRUMP, DONALD J. WRIGHT, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, STEVEN T. MNUCHIN, DEPARTMENT OF THE TREASURY, RENE ALEXANDER ACOSTA AND THE UNITED STATES DEPARTMENT OF LABOR,<br>Defendants. | CIVIL ACTION<br>NO. 17-4540 |

**OPINION**

The interests at stake in this litigation are great, but the issues that must be decided here on Plaintiff's Motion for a Preliminary Injunction are narrow. This case implicates access to healthcare, religious freedom, women's rights, and executive power. However, the Court currently addresses only two precise questions: Did the Defendants here follow the proper procedure in issuing new rules that greatly expand exemptions to the law requiring health plans to cover women's preventive services at no cost, and do the new rules contradict the text of the statute that they are meant to interpret?

Plaintiff, the Commonwealth of Pennsylvania ("Commonwealth"), seeks to enjoin enforcement of two Interim Final Rules ("New IFRs"), referred to as the Moral Exemption Rule and the Religious Exemption Rule, modifying the Affordable Care Act. The New IFRs were issued by the Departments of Health and Human Services, the Department of Treasury and the Department of Labor on October 6, 2017. They permit employers to opt out of providing no-cost contraceptive coverage on the basis of sincerely held religious beliefs or sincerely held moral convictions. The parties here have vastly different perspectives on the import of the New IFRs. The Defendants assert that they are meant to permit a small number of religious objectors to opt out of covering contraceptive services in their employer-sponsored health plans because the requirement to provide contraceptive coverage imposes a substantial burden on their exercise of religion. Quite to the contrary, the Commonwealth argues that the Rules allow almost any employer to withhold insurance coverage for contraceptive services from their female employees, thus impacting millions of women – all in contravention of the Affordable Care Act and the United States Constitution.

The Commonwealth has sued President Donald J. Trump, United States Secretary of Health and Human Services Donald J. Wright,[1] United States Secretary of the Treasury Steven T. Mnuchin, and

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[1] Eric D. Hargan substitutes Donald J. Wright pursuant to Rule 25(d) of the Federal Rules of Civil Procedure.

United States Secretary of Labor Rene Alexander Acosta in their official capacities, as well as each of their agencies (collectively, "Defendants"). It now seeks to enjoin the Defendants from enforcing the New IFRs for a variety of constitutional and statutory violations. For the reasons explained below, the Motion for a Preliminary Injunction shall be granted.

**I. Background**[2]

In March 2010, Congress enacted the Affordable Care Act. *See* Patient Protection and Affordable Care Act (ACA), Pub. L. No. 111-148, 124 Stat. 119 (2010). The ACA included a provision called the Women's Health Amendment, which mandated that group health planshealth insurance issuers offering group or individual health insurance provide coverage for preventive health services and screenings for women without cost-sharing responsibilities. The preventive services that must be covered include, "with respect to women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA)." See 42 U.S.C. § 300gg-13(a)(4). Thus, Congress left the decision about which preventive care and screenings should be covered by the ACA up to the HRSA, which is an agency of the Department of Health and Human Services (HHS).

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[2] The factual statements found here and elsewhere in the opinion constitute this Court's findings of fact, as required under Rule 52(a) of the Federal Rules of Civil Procedure, regardless of any heading or lack thereof.

The HRSA commissioned the Institute of Medicine ("the Institute") to issue recommendations identifying what specific preventive women's health services should be covered under the ACA's mandate. *See* 77 Fed. Reg. 8725-26. The Institute is an arm of the National Academy of Sciences, an organization that Congress established for the explicit purpose of furnishing advice to the federal government. *See Pub. Citizen v. Dep't of Justice*, 491 U.S. 440, 460 n.11 (1989). The Institute, in turn, convened a committee of sixteen members (the "Committee"), including specialists in disease prevention, women's health issues, adolescent health issues, and evidence-based guidelines, to formulate specific recommendations. The Committee defined preventive health services to include measures "shown to improve well-being and/or decrease the likelihood or delay the onset of a targeted disease or condition." Institute, *Clinical Prevention Services for Women: Closing the Gaps* 23 (2011) ("Institute Report").

On July 19, 2011, the Institute, through the Committee, issued a comprehensive report that identified health services that should be covered under the Women's Health Amendment. *Id.* at 8-12. It recommended that the ACA cover "the full range of [FDA]-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity." *Id.* at 109-10. The Committee considered: (1) the prevalence of unintended pregnancy in the United States; (2) potential health risks of pregnancy; (3) that decreased intervals between pregnancies lead to an "increased risk of adverse pregnancy outcomes"; (4) the effectiveness of contraceptives in preventing unintended pregnancy; (5) the health benefits of contraceptives for other diseases and conditions; and (6) the barrier to contraceptive access presented by its cost. *See id.* at 104-10.

*Original Religious Exemption*

On August 1, 2011, HRSA adopted the Institute's recommendations in guidelines, which required, among other things, that plans must cover all FDA-approved contraceptive methods ("Contraceptive Mandate"). 45 C.F.R. § 147.130(a)(1)(iv); 29 C.F.R. § 2590.715- 2713(a)(1)(iv); 26 C.F.R. § 54.9815-2713(a)(1)(iv). This requirement applied to all health insurers offering individual or group insurance, as well as all group health plans, with the exception of certain "grandfathered" plans. *See* 29 C.F.R. § 2590.715-1251. Simultaneously, the Departments of HHS, Labor, and the Treasury ("the Agencies" or "Defendant Agencies") also promulgated an Interim Final Rule ("IFR") exempting certain religious employers from providing contraceptive services ("Original Religious Exemption"). *See* 76 Fed. Reg. 46621. To take advantage of that exemption, an employer must: (1) have the inculcation of religious values as its purpose; (2) primarily employ people who share its religious tenets; (3) primarily provide services to persons who share its religious tenets; and, (4) be a church, its integrated auxiliary, or a convention or association of a church, all of which are exempt from taxation under 26 U.S.C. § 501(a). *See id.* at 46623.

*Second Religious Exemption and Accommodation Process*

Following several legal challenges to the Contraceptive Mandate, the Agencies began to consider changes to the religious exemptions. In March 2012, they issued an Advanced Notice of Proposed Rulemaking concerning a potential accommodation process for religious objectors to the Contraceptive Mandate. 77 Fed. Reg. 16501. After a comment period, they then issued a Notice of Proposed Rulemaking proposing changes to the definition of religious organizations in the exemption and creating an accommodation process for religious objectors to the Contraceptive Mandate. 78 Fed. Reg. 8456. The Agencies published final regulations on July 2, 2013 ("Second Religious Exemption"). *See* 78 Fed. Reg. 39870. These regulations redefined a religious employer to only refer to churches, their integrated auxiliaries, and conventions or associations of churches, eliminating the need to fulfill the first three requirements of the prior regulations of the exemption. Upon a covered entity claiming the exemption, the provider or administrator would then have to provide the legally required contraceptive services directly to women covered under the employer's plan ("Accommodation Process").

*Third Religious Exemption and Accommodation Process*

Following enactment of the ACA and the Second Religious Exemption, the Supreme Court granted certiorari to decide whether the Contraceptive Mandate violated the Religious Freedom Restoration Act, 42 U.S.C. § 2000bb-1 (RFRA). In *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014), the Supreme Court concluded that applying the Contraceptive Mandate to closely held corporations violated RFRA. In *Wheaton Coll. v. Burwell*, 134 S.

Ct. 2806 (2014), the Court identified an alternative process by which Wheaton College could comply with the Contraceptive Mandate without informing its health insurer or third-party administrator: The Court permitted Wheaton College to "inform[] the Secretary of Health and Human Service in writing that it . . . has religious objections to providing coverage for contraceptive services. *Id.* at 2807. In response to *Hobby Lobby* and *Wheaton College*, the Agencies issued a third set of IFRs to augment the Accommodation Process to comply with the Supreme Court's orders. *See* 79 Fed. Reg. 51092, 51118 (expanding the Accommodation Process to include for-profit corporations and to adjust the Accommodation Process). The Agencies finalized the IFRs on July 14, 2015 ("Third Religious Exemption"). See 80 Fed. Reg. 41318, 41324.

One year later, the Supreme Court granted certiorari to decide whether the Accommodation Process violated RFRA. The question before the Supreme Court was whether the requirement to notify plaintiffs' insurers of their religious objections substantially burdened their exercise of religion in violation of RFRA. The Supreme Court did not address the question head on. Rather, it vacated the judgments of the courts of appeals and remanded the cases to provide the parties "an opportunity to arrive at an approach going forward that accommodates petitioners' religious exercise while at the same time ensuring that women covered by petitioners' health plans 'receive full and equal health coverage, including contraceptive coverage.'" *Zubik v. Burwell*, 136 S. Ct. 1557, 1560 (2016). The Agencies then issued a Request for Information ("RFI") seeking public comment on options for modifying the

Accommodation Process in light of *Zubik*. *See* 81 Fed. Reg. 47741. On January 9, 2017, the Department of Labor announced that it was unable to develop an approach that could "resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage." Department of Labor, *FAQs about Affordable Care Act Implementation Part 36* (Jan. 9, 2017).

*Executive Order 13798: "Promoting Free Speech and Religious Liberty"*

On May 4, 2017, President Trump issued an Executive Order "Promoting Free Speech and Religious Liberty." Exec. Order No. 13798, 82 Fed. Reg. 21675. The Order directed the Agencies to "consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive-care mandate promulgated under [the Women's Health Amendment.]" *Id*. § 3.

*Fourth Religious Exemption and Accommodation Process*

The Agencies issued the New IFRs on October 6, 2017, citing a goal of being "consistent with the President's Executive Order and the Government's desire to resolve the pending litigation and prevent future litigation from similar plaintiffs." *See* 82 Fed. Reg. 47792 ("Religious Exemption Rule"); 82 Fed. Reg. 47838 ("Moral Exemption Rule"). The New IFRs embodied two exemptions to the Contraceptive Mandate. First, under the Religious Exemption Rule, any non-profit or for-profit entity, whether closely held or publicly traded, may claim the exemption based on sincerely held religious beliefs. Second, under the Moral Exemption Rule, any non-profit or for-profit entity, so long as it is closely held, may claim the exemption based on sincerely held moral convictions.

The Religious Exemption and Moral Exemption Rules make significant changes from prior exemptions. First, the new rules greatly expand the scope of who may opt out of the Contraceptive Mandate. Second, the rules render the Accommodation Process optional. Third, they eliminate requirements to provide notice of an intent to take advantage of either exemption. In other words, entities that stop providing contraceptive care "do not need to file notices or certifications of their exemption and [the Exemption Rules] do not impose any new notice requirements on them."[3] *See* 82 Fed. Reg. 47850, 47858. Fourth, the New IFRs permit employers to opt out of coverage on the basis of "sincerely held" religious beliefs and moral convictions.

The Agencies issued the new rules as IFRs and requested post-issuance comments by December 5, 2017, 60 days after they were issued. The Commonwealth filed this suit in the interim seeking to enjoin enforcement of the New IFRs because: (1) they fail to comply with the notice-and-comment procedures required by the Administrative Procedure Act ("APA"), 5 U.S.C. § 551, *et seq.*; (2) they are

[3] The Employee Retirement Income Security Act of 1974 (ERISA) still requires group health plans to notify plan participants of any change in coverage at least 30 or 60 days in advance. *See* 77 Fed. Reg. 8667.

"arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" in violation of the substantive provisions of the APA, 5 U.S.C. § 706(2)(A); (3) they violate Title VII of the Civil Rights Act, 42 U.S.C. § 2000-2(a); (4) they violate the Equal Protection Guarantee of the Fifth Amendment, U.S. Const. amend. V; and, (5) they violate the Establishment Clause. U.S. Const. amend. I.

**II. Standing**

A threshold question is whether the Commonwealth has standing. Standing is a litigant's ticket to federal court. It is a constitutional requirement, "limit[ing] the category of litigants empowered to maintain a lawsuit in federal court to seek redress for a legal wrong." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016); U.S. Const. art. III, § 2, cl. 2. The Commonwealth contends that it is properly before the Court because the New IFRs are causing, or will imminently cause, direct harm to its sovereign, quasi-sovereign and proprietary interests. Additionally, it asserts that it has *parens patriae* standing to protect the health, safety and well- being of its residents in ensuring that they enjoy access to healthcare services. The Defendants, on the other hand, contend that the Commonwealth has not suffered any legal wrong that would allow it to step foot into federal court.

"No principle is more fundamental to the judiciary's proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases or controversies." *Raines v. Byrd*, 521 U.S. 811, 818 (1997). The doctrine of standing ensures that federal judicial power is properly limited to these cases or controversies. *See*

*Finkleman v. Nat'l Football League*, 810 F.3d 187, 203 (3d Cir. 2016). Thus, if a plaintiff lacks standing, the case must be dismissed. *See id.* at 195. And, as Plaintiff, the Commonwealth has the burden of establishing that it has standing. *See Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 411-12 (2013).

To do so, it must satisfy "the irreducible constitutional minimum of standing," which "contains three elements." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). First, the Commonwealth must have suffered an "injury in fact," defined as "an invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical." *Id.* (internal quotation marks and citations omitted). Second, the Commonwealth must show that there is a "causal connection between the injury and the conduct complained of." *Id.* That is, the injury must be "fairly traceable" to the "challenged action of the defendant." *Id.* Third, the Commonwealth must show that it is "likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Id.* at 561 (internal quotation marks omitted). "Each element [of standing] must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, *i.e.*, with the manner and degree of evidence required at the successive stages of the litigation." *Id.* Thus, because the Commonwealth here seeks a preliminary injunction, it must adduce evidence demonstrating more than a mere possibility of injury in support of standing. *Doe v. Nat'l Bd. of Med. Exam'rs*, 199 F.3d 146, 152 (3d Cir. 1999).

**a. Special Solicitude**

This standing inquiry must be made in the context of a clear recognition that States, like the Commonwealth here, "are not normal litigants for the purposes of invoking federal jurisdiction." *Massachusetts v. EPA*, 549 U.S. 497, 518 (2007). Accordingly, a State is "entitled to special solicitude in [the] standing analysis" if it has: (1) a procedural right that authorizes it to challenge the conduct at issue; and, (2) a "stake in protecting its quasi-sovereign interests." *Massachusetts*, 549 U.S. at 520; *see also Texas v. United States*, 809 F.3d 134, 151 (5th Cir. 2015), *aff'd by an equally divided Court*, 136 S. Ct. 2271 (2016).

In determining whether the Commonwealth has met these conditions, both *Massachusetts v. EPA* and *Texas v. United States* are instructive. In *Massachusetts v. EPA*, Massachusetts sued the Environmental Protection Agency (EPA), alleging that global warming was "the most pressing environmental challenge of our time," and that the EPA had "abdicated its responsibility under the Clean Air Act" when it failed to issue rules regulating the emission of greenhouse gases coming from cars. 549 U.S. at 505. The EPA challenged Massachusetts' standing to bring the suit because greenhouse gas emissions are a widespread and generalized harm not unique to any specific plaintiff. *See id.* at 517. The Supreme Court nonetheless held that Massachusetts had special solicitude in the standing inquiry to challenge the EPA's inaction: First, Massachusetts had a procedural right under the relevant statute, the Clean Air Act, which allowed it to "challenge agency action unlawfully withheld." *Id.* (citing 42

U.S.C. § 7607(b)(1)). Second, Massachusetts had a quasi-sovereign interest – a "well-founded desire to preserve its sovereign territory" from the effects of global warming. *Id.* at 519. Indeed, Massachusetts "own[ed] a great deal of the 'territory alleged to be affected.'" Id.; see also id. at 522 (affidavits noting that "rising seas have already begun to swallow Massachusetts' coastal land."). After concluding that Massachusetts was entitled to special solicitude in the standing analysis, the Supreme Court ultimately held that it had Article III standing to sue the EPA based on an injury to its territory that stemmed from global warming. *See id.* at 526.

In *Texas v. United States*, the Fifth Circuit, relying on *Massachusetts v. EPA*, similarly concluded that Texas, as a State, was entitled to special solicitude in seeking to enjoin implementation of the Deferred Action for Parents of Americans and Lawful Permanent Residents program (DAPA). 809 F.3d at 154. In that case, non-citizens in Texas could apply for a driver's license if they presented "documentation issued by the appropriate United States agency that authorizes the applicant to be in the United States." *See id.* at 155 (quoting TEX. TRANSP. CODE § 521.142(a)). DAPA would have permitted at least 500,000 non-citizens to qualify for these driver's licenses. *Id.* Because Texas subsidized its licenses, it would have lost money for each license issued to a DAPA beneficiary. *Id.* Texas therefore sought injunctive relief to prevent DAPA's implementation. *See id.* at 149.

Applying the *Massachusetts v. EPA* framework, the Fifth Circuit first considered whether Texas had a procedural right to challenge DAPA. It concluded that Texas' use of the APA to challenge an "affirmative decision" made by a federal agency was similar to Massachusetts' use of the judicial review provision in the Clean Air Act to challenge the EPA's inaction. *Id.* at 152. Second, as to Texas' quasi-sovereign interest, the Fifth Circuit held that DAPA imposed "substantial pressure" on the State to change its laws to avoid bearing further costs from subsidizing additional driver's licenses. *See id.* at 153. The Fifth Circuit thus concluded that Texas had special solicitude in suing the federal government under the APA for injunctive relief. *Id.* at 154-55.

On writ of certiorari, the Supreme Court summarily affirmed the Fifth Circuit's decision without opinion but with a notation that the affirmance was "by an equally divided Court." *United States v. Texas*, 136 S. Ct. 2271 (2016) (per curiam). Notably, one question certified by the Supreme Court included whether Texas had standing. *See United States v. Texas,* 136 S. Ct. 906 (2016) (granting petition for writ of certiorari for, among other things, whether Texas had standing). Affirmances by an equally divided Supreme Court typically do not constitute binding precedent. *See Eaton v. Price*, 364 U.S. 263, 264 (1960). However, when the Supreme Court is equally divided on an issue of subject matter jurisdiction, it has determined that the proper course is to remand the issue of jurisdiction to a lower court. *See Silliman v. Hudson River Bridge Co.*, 66 U.S. 582, 584-85 (1861). In other words, if the Supreme Court were equally divided on whether Texas had standing to enjoin DAPA, it would have remanded that issue to the Fifth Circuit. The Supreme Court did not and instead affirmed the Fifth Circuit. It therefore follows logically that a majority of the

Supreme Court decided that Texas had standing to pursue its APA claim.[4]

There is no daylight between the 2015 Texas suit against the federal government and the current Commonwealth suit against the federal government. Like Texas, the Commonwealth challenges agency action in issuing regulations – here, the New IFRs. *See Texas*, 809 F.3d at 152. It is all the more significant that the Commonwealth, like Texas before it, sues to halt *affirmative* conduct made by a federal agency. *See id.* Whereas *Massachusetts v. EPA* concerned regulatory inaction – the EPA's order denying a rulemaking petition – the Commonwealth's case here challenges regulatory action that, it contends, affects its legally cognizable interests. *See* 549 U.S. at 514. Thus, it is especially appropriate to accord the Commonwealth "special solicitude." *Texas*, 809 F.3d at 152-53. Furthermore, like Texas and Massachusetts, the Commonwealth seeks to protect a quasi-sovereign interest – the health of its women residents. *See Alfred L. Snapp & Son, Inc. v. Puerto Rico*, 458 U.S. 592, 600-01 (1982) (holding that a State has a "quasi-sovereign interest in the health and wellbeing – both physical and economic – of its residents in general."). As the Commonwealth observes, contraceptives offer significant health benefits, including the prevention of unintended pregnancies, and the treatment of menstrual disorders, acne or hirsutism, and pelvic pain. This quasi-sovereign interest in safeguarding the health

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[4] Even if the affirmance by an equally divided Supreme Court as it relates to subject matter jurisdiction were not binding, the Court is persuaded by the reasoning of the Fifth Circuit in *Texas v. United States* as it pertains to state standing.

and wellbeing of its women residents is inextricably intertwined with the Commonwealth's alleged future fiscal injury that, as will be discussed later, goes to the heart of its Article III standing. *See Texas*, 809 F.3d at 153 (concluding that DAPA affected quasi-sovereign interest by "imposing substantial pressure" on Texas to change its laws to avoid losing more money from driver license subsidies). According to the Commonwealth (and as addressed more fully below), the Agencies' New IFRs will allow more employers to exempt themselves from the ACA's Contraceptive Mandate. Consequently, the Commonwealth contends that Pennsylvanian women will seek state-funded sources of contraceptive care. Such a course of action will likely cause the Commonwealth to expend more funds to protect its quasi- sovereign interest in ensuring that women residents receive adequate contraceptive care. The Commonwealth, then, meets the two conditions outlined in *Massachusetts v. EPA* and shall be accorded special solicitude in the standing analysis.

**b. Article III Standing**

As previously stated, the three pillars of standing are injury in fact, causation, and redressability. *Lujan*, 504 U.S. at 560. First, an agency rule that has "a major effect on the states' fiscs" is sufficient to find injury in fact. *Texas*, 809 F.3d at 152; id. at 155 (Texas "satisfied the first standing requirement by demonstrating that it would incur significant costs in issuing driver's licenses to DAPA beneficiaries."); *see also Wyoming v. Oklahoma*, 502 U.S. 437, 448 (1992) (holding that Wyoming had Article III standing because it undisputedly suffered a "direct injury in the form of a loss of specific tax revenues"); *Danvers*

*Motor Co., Inc. v. Ford Motor Co.*, 432 F.3d 286, 291 (3d Cir. 2005) ("While it is difficult to reduce injury-in-fact to a simple formula, economic injury is one of its paradigmatic forms.").

The New IFRs will likely inflict a direct injury upon the Commonwealth by imposing substantial financial burdens on State coffers. Specifically, the Commonwealth will have to increase its expenditures for State and local programs providing contraceptive services. This is not a speculative harm. As the Defendants themselves noted in issuing one of the New IFRs, "there are multiple Federal, State, and local programs that provide free or subsidized contraceptives for low-income women." 82 Fed. Reg. 47803. As more women residents of the Commonwealth are deprived of contraceptive services through their insurance plans and turn to these State and local programs, the Commonwealth will likely make greater expenditures to ensure adequate contraceptive care. And although Defendants point out that the Commonwealth has not yet identified a woman resident of Pennsylvania who has lost contraceptive coverage as a result of the New IFRs, the Commonwealth need not sit idly by and wait for fiscal harm to befall it. *See McNair v. Synapse Group Inc.*, 672 F.3d 213, 223 (3d Cir. 2012) ("When, as in this case, prospective relief is sought, the plaintiff must show that he is "likely to suffer future injury" from the defendant's conduct.") (quoting *City of Los Angeles v. Lyons*, 461 U.S. 95, 105 (1983)). As the New IFRs themselves estimate, they will cause at least 31,700 women to lose contraceptive coverage. 82 Fed. Reg. 47821.

Indeed, the Commonwealth's affidavits confirm that its women residents will come to rely more on State-funded sources. The Acting Executive Deputy Secretary for the Commonwealth's Department of Human Services concludes that it would not be unreasonable to expect women who do not receive contraceptive care from their insurers to rely on government- funded programs. *See* Decl. of Leesa Allen ¶ 23 ("Allen Decl."). The Executive Deputy Insurance Commissioner for the Commonwealth echoes a similar view, expecting women who lose contraceptive coverage to seek coverage from State-funded programs (or pay for the contraceptives themselves). See Decl. of Seth A. Mendelsohn ("Medelsohn Decl.") ¶ 15. The CEO of Planned Parenthood Southeastern Pennsylvania also expects that, as a result of the New IFRs, many low-income women will have to rely on government-funded programs to obtain contraceptive care. See Decl. of Dayle Steinberg ("Steinberg Decl.") ¶¶ 24-25. The Commonwealth has furthermore provided evidence from a doctor who practices in Pennsylvania acknowledging that she directs uninsured, low-income women to State programs for contraceptive services. *See* Tr. 177-78. At bottom, just as Texas' estimated loss due to DAPA supported injury in fact, so too does the Commonwealth's estimated loss due to the New IFRs support injury in fact. *See Texas*, 809 F.3d at 155.

Second, the Commonwealth's financial injury is "fairly traceable" to issuance of the New IFRs. By their terms, they expand the scope of the existing religious exemption rule as well as allow employers a new rationale for refusing to provide employees with contraceptive coverage if the refusal is "based on sincerely held moral convictions." In short, the New IFRs allow more employers to stop providing contraceptive coverage. And as the Commonwealth's various affidavits show, State officials expect that once employers take advantage of the New IFRs more women residents will seek contraceptive care through State-funded programs. The Commonwealth has thus shown a causal connection between the New IFRs and its financial injury.

Defendants, however, cite to *Pennsylvania v. New Jersey*, 426 U.S. 660, 664 (1976), and argue that the injury is not "fairly traceable" to the New IFRs because the Commonwealth's fiscal injury is "self-inflicted." According to Defendants, the Commonwealth cannot shoot itself in the foot and then hobble into federal court by premising injury in fact on costs that flow from *elective* State programs that offer contraceptive care services to residents.

*Pennsylvania v. New Jersey* is distinguishable. In that case, Pennsylvania voluntarily gave tax credits to Pennsylvania residents who paid taxes in New Jersey. *Id.* at 663. Pennsylvania proceeded to sue New Jersey, contending that the New Jersey tax injured Pennsylvania's fiscs and was constitutionally impermissible. *Id.* at 662. The Supreme Court found that Pennsylvania lacked standing because the injuries to its fiscs were "self-inflicted," resulting, as they did, from a decision of its state legislature. *Id.* at 664. Pennsylvania was not allowed to "complain about damage inflicted by its own hand" when it enacted a law that incorporated the legislative choices of New Jersey. *Id.* The harm could have been avoided if Pennsylvania simply changed the law so that it no longer extended credits for taxes paid to

New Jersey. *See id.* Here, by contrast, funding for the Commonwealth's programs does not explicitly incorporate the legislative choices of the federal government. Rather, the Commonwealth's described injuries flow from the unilateral decision by the Agencies to issue the New IFRs, which will likely cause Pennsylvanian women to seek contraceptive care from other sources, particularly state-funded sources. Consequently, the injunction that the Commonwealth seeks – to enjoin that unilateral federal agency decision – is untethered to any state law that the Commonwealth itself has enacted. *See Texas*, 809 F.3d at 158 ("The fact that Texas sued in response to a significant change in the defendants' policies shows that its injury is not self- inflicted.").

Third, the Commonwealth has satisfied the redressability requirement. Because the Commonwealth is asserting a procedural right under the APA to protect its interests, it "can assert that right without meeting all the normal standards for redressability and immediacy." *See Massachusetts*, 549 U.S. at 517-18. If, as here, the litigant is "vested with a procedural right, that litigant has standing if there is some possibility that the requested relief will prompt the injury- causing party to reconsider the decision that allegedly harmed the litigant." *Id.* at 518. Enjoining the Agencies' New IFRs based on APA claims should prompt them to reconsider the propriety of the Religious and Moral Exemptions Rules, "which is all a plaintiff must show when asserting a procedural right." *Texas*, 809 F.3d at 161. In sum, the Commonwealth has shown that it has standing to pursue injunctive relief through its APA claims based on an injury to its fiscs.[5]

### III. Legal Standard

As the Commonwealth has standing to pursue a preliminary injunction, the next step is to determine whether one is appropriate. A preliminary injunction is an extraordinary remedy; it "should be granted only in limited circumstances." *American Tel. & Tel. Co. v. Winback & Conserve Program, Inc.*, 42 F.3d 1421, 1426-27 (3d Cir. 1994). "A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). The "failure to establish any element . . . renders a preliminary injunction inappropriate." *NutraSweet Co. v. Vit–Mar Enters., Inc.*, 176 F.3d 151, 153 (3d Cir. 1999). The movant bears the burden of showing that these four factors weigh in favor of granting the injunction. See Opticians Ass'n of Am. *v.* Indep. Opticians of Am., 920 F.2d 187, 192 (3d Cir. 1990).

While the movant must show that each of these factors weighs in favor of granting an injunction, an injunction might be appropriate where a movant makes a particularly strong case on some factors, but not others. Thus, "courts must *balance* the competing

[5] Because the Commonwealth has identified an imminent, direct injury to its state coffers that result from the New IFRs, the Court does not need to address whether it has sovereign or *parens patriae* standing.

claims of injury and must consider the effect on each party of the granting or withholding of the requested relief." *Reilly v. City of Harrisburg*, 858 F.3d 173, 177-78 (3d Cir. 2017), *as amended* (June 26, 2017) (quoting *Winter*, 555 U.S. at 24). "[I]n a situation where factors of irreparable harm, interests of third parties and public considerations strongly favor the moving party, an injunction might be appropriate even though plaintiffs did not demonstrate as strong a likelihood of ultimate success as would be generally required." *Constructors Ass'n of W. Pa. v. Kreps*, 573 F.2d 811, 815 (3d Cir. 1978). In addition, the court must weigh "[a]ll of [the four preliminary injunction] factors . . . together in the final decision and the strength of the plaintiff's showing with respect to one may affect what will suffice with respect to another." *Marxe v. Jackson,* 833 F.2d 1121, 1128 (3d Cir. 1987). The Third Circuit recently clarified in *Reilly* that a "movant for preliminary equitable relief must meet the threshold for the first two 'most critical' factors [– likelihood of success and irreparable harm]. If these gateway factors are met, a court then considers the remaining two factors and determines in its sound discretion if all four factors, taken together, balance in favor of granting the requested preliminary relief." Reilly, 858 F.3d at 179. "How strong a claim on the merits is enough depends on the balance of the harms: the more net harm an injunction can prevent, the weaker the plaintiff's claim on the merits can be while still supporting some preliminary relief." *Id.*

**a. Likelihood of Success on the Merits**

In demonstrating the likelihood of success on the merits, a plaintiff need not show that it is more likely than not that he will succeed. *Singer Mgmt.*

*Consultants, Inc. v. Milgram*, 650 F.3d 223, 229 (3d Cir. 2011) (en banc). Instead, a plaintiff must "show[] a reasonable probability of success on the merits." *American Express Travel Related Svcs., Inc. v. Sidamon– Eristoff*, 669 F.3d 359, 366 (3d Cir. 2012). This requires a showing "significantly better than negligible, but not necessarily more likely than not." *Reilly*, 858 F.3d at 179.

Because "courts should be extremely careful not to issue unnecessary constitutional rulings," *American Foreign Serv. Ass'n v. Garfinkel*, 490 U.S. 153, 161 (1989) (per curiam), the Court addresses the statutory claims at issue – that Defendants violated the notice-and-comment procedures of the APA and that the New IFRs are "arbitrary, capricious, or not in accordance with law" – and finds it unnecessary, at this juncture, to proceed to the constitutional issues.

**i. Administrative Procedure Act**

**1. Procedural Safeguards**

The APA provides any interested party the right to participate in the rulemaking process by submitting data, views or arguments. *See* 5 U.S.C. § 553. "The APA provisions reflect a judgment by Congress that the public interest is served by a careful and open review of proposed administrative rules and regulations." *Phila. Citizens in Action v. Schweiker*, 669 F.2d 877, 881 (3d Cir. 1982). "Section 553 was enacted to give the public an opportunity to participate in the rule-making process. It also enables the agency promulgating the rule to educate itself before establishing rules and procedures which have a substantial impact on those regulated."

*Texaco, Inc. v. Fed. Power Comm'n*, 412 F.2d 740, 744 (3d Cir. 1969).

Accordingly, prior to promulgating regulations, administrative agencies must follow a procedure called "notice and comment rulemaking." *See* 5 U.S.C. § 553. First, an agency must issue a general notice of proposed rulemaking. *See* 5 U.S.C. §§ 552(b), 553(b). Then the agency must "give interested persons an opportunity to participate in the rule making through submission of written data, views or arguments . . . . " *Id.* § 553(c). Last, "[a]fter consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose." *Id.* Defendants bypassed each of these procedures when issuing the New IFRs.

The APA requires a court to set aside agency action "found to be . . . without observance of procedure required by law." 5 U.S.C. § 706(2)(D). Thus, if Defendants did not comply with notice and comment provisions, the Court must preliminarily enjoin Defendants from enforcing the New IFRs unless there is a statutorily countenanced reason for their non-compliance. *See Minard Run Oil Co. v. U.S. Forest Serv.*, 2009 WL 4937785, at *34 (W.D. Pa. 2009), *aff'd*, 670 F.3d 236 (3d Cir. 2011).

Although "[e]xemption from the terms of the Administrative Procedure Act are not lightly to be presumed . . . ," *Marcello v. Bonds*, 349 U.S. 302, 310 (1955), there are limited exceptions to the requirement that all rules must be issued pursuant to notice-and-comment rulemaking. Defendants contend that two of those exceptions apply here. First, they argue that Congress expressly and impliedly authorized the Secretaries of HHS, Labor, and the Treasury to bypass notice and comment rulemaking with respect to the New IFRs. 5 U.S.C. § 559. Second, they argue that there is no need for notice-and-comment rulemaking because they have found "good cause" that the notice and comment procedure is, in this instance, "impracticable, unnecessary, or contrary to the public interest." *Id.* § 553(b)(B).

*i. Statutory Authorization to Bypass Notice and Comment*

At the outset, it should be noted that the ACA contains no provision expressly authorizing the Defendant Agencies or their respective Secretaries to bypass the APA's notice and comment requirements, and indeed, Defendants cite none. Rather, in justifying their sidestep of the strictures of the notice and comment procedure, they find express and implied authorizations for their actions through various statutes *besides* the ACA. Defendants' argument, matryoshkanesque in its construction, proceeds as follows: In 1996, Congress passed the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191 (1996), which regulates group health plans and some individual health insurance policies. HIPAA amended certain provisions of the United States Code to provide that "[t]he [respective] Secretary may promulgate any interim final rules as the Secretary determines are appropriate to carry out this [chapter.]" See 29 U.S.C. § 1191c; 26 U.S.C. § 9833; 42 U.S.C. § 300gg-92.[6] In

[6] Specifically, HIPAA amended various portions of ERISA, which is administered by the Secretary of Labor, the Internal Revenue Code, which is administered by the Secretary of

2010, Congress passed the ACA, which also amended those same sections of the United States Code to require health plans to cover certain preventive women's services. HHS interpreted the preventive service requirement to include contraceptive services. The requirement to provide contraceptive services was thus codified in the chapters of the United States Code as modified by HIPAA in 1996. Thus, according to Defendants, HIPAA's amendments, which permit issuance of IFRs "appropriate to carry out this [chapter]," also encompass authorization to issue IFRs to carry out the ACA.

The argument is creative, but not supported by law. As to express authorization, in order to authorize an agency to bypass notice and comment, a subsequent statute must be clear that it abrogates the APA. See 5 U.S.C. § 559; *Coalition for Parity, Inc. v. Sebelius*, 709 F. Supp. 2d 10, 18 (D.D.C. 2010). And as *Coalition for Parity* held, the provision of HIPAA that Defendants here rely on says nothing about overruling the APA, let alone notice and comment procedures. *Id.* HIPAA, then, does not provide express authorization to bypass the notice and comment requirements of the APA in this case. *See id.*

As to implied authorization, the relevant standard to determine if Congress *sub silentio* allowed an agency to avoid notice and comment is "whether Congress has established procedures so clearly different from those required by the APA that it must have intended to displace the norm." *Asiana Airlines*

Treasury, and the Public Health Services Act, which is administered by the Secretary of Health and Human Services.

*v. FAA*, 134 F.3d 393, 397 (D.C. Cir. 1998). Defendants rely on two cases, *Asiana Airlines and Methodist Hospital of Sacramento v. Shalala*, 38 F.3d 1225, 1237 (D.C. Cir. 1994), for the proposition that Congress has impliedly authorized the Agencies here to bypass notice and comment and issue IFRs.

In both *Asiana Airlines and Methodist Hospital*, the D.C. Circuit held that certain IFRs could be issued without complying with notice and comment, but both cases are inapposite. The statutory language from those cases, involving respectively the Federal Aviation Reauthorization Act and the Social Security Amendments of 1983, expressly abrogated APA notice and comment procedures because Congress, through its use of the mandatory word "shall" in both pieces of legislation, commanded the agencies to issue interim final rules. *See Asiana Airlines*, 134 F.3d at 395 ("the Administrator **shall** publish . . . interim final rule[s]") (citing 49 U.S.C. § 45301(b)(2)) (emphasis added); *Methodist Hosp.*, 38 F.3d at 1236 n.18 ("[t]he Secretary **shall** cause to be published . . . a notice of the interim final DRG prospective payment rates . . . without the necessity for consideration of comments . . . ") (citing 97 Stat. 168-69) (emphasis added). By contrast, the HIPAA provision here states that a "Secretary **may** promulgate any interim final rules as the Secretary determines are appropriate . . . . " *See* 29 U.S.C. § 1191c; 26 U.S.C. § 9833; 42 U.S.C. § 300gg-92 (emphasis added). The use of the term "may" is permissive rather than mandatory. See *Barlow v. Collins*, 397 U.S. 159, 165-66 (1970) (statute authorizing Secretary of Agriculture to promulgate regulations "as he may deem proper" does not preclude judicial review).[7] There is, accordingly, no support in HIPAA for the Agencies' avoidance of the notice and comment procedure.

*ii. Good Cause Exception to Bypass Notice and Comment*

The second exception to notice-and-comment rulemaking permits agencies to utilize IFRs "for good cause." See 5 U.S.C. § 553. More specifically, the APA provides that notice and comment may be waived "when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." *Id.* The "circumstances justifying reliance on the good cause exception are 'indeed rare' and will be accepted only after the court has examined closely proffered rationales justifying the elimination of public procedures." *Natural Res. Def. Council, Inc. v. EPA*, 683 F.2d 752, 764 (3d Cir. 1982). The Third Circuit has cautioned that the good cause exception should be "narrowly construed." *United States v. Reynolds*, 710 F.3d 498, 507 (3d Cir. 2013) (citations omitted).

Since the APA requires agencies availing themselves of the good cause exception to state their "finding[s] and a brief statement of reasons" for good cause "in the rules issued," the Court will examine

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[7] *Asiana Airlines* and *Methodist Hospital* are further distinguishable still. In both cases, Congress imposed an expeditious timetable on the agencies in issuing the IFRs which justified bypassing notice and comment. *See Methodist Hosp.*, 38 F.3d at 1237; *Asiana Airlines*, 124 F.3d at 398. By contrast, the supposed statutory authorization in HIPAA provides no timetable for the Agencies to issue IFRs.

the proffered "good cause" reasons as stated in the New IFRs. *See* 82 Fed. Reg. at 47813-15; 82 Fed. Reg. at 47855-59. First, the Agencies found that excessive delay caused by notice and comment rulemaking would be contrary to public interest. *Id.* Second, the Agencies determined that the New IFRs were important to resolve ongoing litigation and ease the burdens imposed by them in order to prevent "continued uncertainty, inconsistency, and cost." *Id.* Third, the Agencies determined that they had already received significant comments in past rounds of rulemaking as well as from the 2016 RFI, and therefore there was no need to repeat the notice- and-comment process again. *Id.* These arguments are considered seriatim.

As to their "excessive delay" justification, the Agencies contend that, because the Accommodation Process (in their view) violated RFRA, it was a matter of urgency to issue the New IFRs without going through the APA's time-consuming notice and comment process.[8] *See id.* However, urgency is not

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[8] The Agencies also justify their use of IFRs rather than regulations promulgated through APA's proscribed procedures by reference to their use of IFRs in three earlier updates to regulations concerning the Women's Health Amendment. This fact does not, of course, warrant a conclusion that the New IFRs were appropriately issued – the facts of one case do not necessarily transfer wholesale to another. Defendants argue that as the D.C. Circuit upheld the Defendants' use of IFRs in *Priests for Life v. U.S. Dep't of Health and Human Servs.*, 772 F.3d 229, 276 (D.C. Cir. 2014), *vacated on other grounds*, *Zubik v. Burwell*, 136 S. Ct. 1557 (2016), this Court should do so here. In that case, however, the D.C. Circuit reasoned that good cause existed to bypass notice and comment because "the regulations the interim final rule modifies were recently enacted pursuant to notice and comment rulemaking, [] present virtually identical

sufficient in the absence of a deadline imposed by Congress, the executive, or courts. *See Reynolds*, 710 F.3d at 511 ("Our prior decisions have recognized urgency alone as sufficient only when a deadline imposed by Congress, the executive, or the judiciary requires agency action in a timespan that is too short to provide a notice and comment period."). None of the three branches of government have imposed any urgent deadline that could support circumventing notice and comment rulemaking. First, Congress has not spoken on this issue. Second, far from compelling any immediate action, President Trump's Executive Order 13798 merely asks the Secretaries to "consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive care mandate." Executive Order 13798 § 3. Last, the Supreme Court has not imposed any deadline or called for urgent action either. In fact, the Supreme Court remanded the latest challenge to the Accommodation Process to give the parties "an opportunity to arrive at an approach going forward." *Zubik*, 136 S. Ct. at 1560. Though Defendants cite many cases in which courts have pressured them to resolve uncertainty regarding the Contraceptive Mandate, none of those courts have imposed any actual deadlines for issuing regulations.

"The desire to eliminate uncertainty, by itself, cannot constitute good cause." *Reynolds*, 710 F.3d at

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issues, . . . the modifications made in the interim final rule are minor," and the Supreme Court "obligat[ed] [HHS] to take action." *Id.* By contrast, the issues presented in the New IFRs are not identical to prior regulations, they make significant changes in the law, and the Supreme Court did not require immediate action.

510. Even if it could, the Agencies' stated need to resolve uncertainty is undercut by the request, contained in the New IFRs, for post-issuance comments regarding "whether these regulations expanding the exemption should be made permanent or subject to modification." *See* 82 Fed. Reg. at 47814-15; 82 Fed. Reg. at 47855-56. The request for comments particularly as to whether the New IFRs should be modified "implicitly suggests that the rule[s] will be reconsidered [and] means the level of uncertainty is, at best, unchanged. . . ." *Reynolds*, 710 F.3d at 511.

The Agencies stated in the New IFRs that the clarity offered by the expanded exemptions will decrease insurance costs; they hypothesize that groups with grandfathered health plans will wish to make changes to other components of their health plans in order to reduce costs, while still avoiding coverage for contraceptive services. *See* 82 Fed. Reg. 47815, 47856. Under the ACA, as long as grandfathered plans do not make any changes to their health coverage, they need not cover women's preventive services. However, the New IFRs do not cite a single comment from an employer with a grandfathered plan which suggests that they will make changes to health plans in light of the new agency interpretation.[9] This is merely speculation, unsupported by the record.

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[9] Indeed, a search of "grandfather" in the hundreds of thousands of pages of the Administrative Record filed with the Court does not reveal a single comment from a policy holder with a grandfathered health plan who sought to change their health coverage without risking their grandfathered status. During Oral Argument, the Court asked Defendants to find comments

Last, the Agencies asserted in the New IFRs that notice and comment was unnecessary because the Agencies considered past comments and requested post-issuance comments. The Agencies received multiple rounds of comments on the first set of interim final regulations in 2010, on the interim final regulations in 2011, on the proposed changes to the religious employer exemption in 2012 and 2013, on the modifications to the Accommodation Process in 2015, and on the RFI issued in July 2016. And the Agencies received over 54,000 public comments in response to the July 2016 RFI which sought ways to expand the Accommodation Process.

Defendants cite no case, and research has not disclosed any, finding that notice and comment is unnecessary where an agency has received ample commentary on its prior interpretations of the same law. In fact, the significance of this issue and the outpouring of public comments reflect the opposite: the overwhelming public interest demonstrates that notice and comment is critical. "The unnecessary prong of the exception . . . 'is confined to those

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in the Administrative Record demonstrating that group health plans with grandfathered status sought to change their health plans without forgoing their grandfathered status. Defendants admitted that they "have identified no particular comments." Tr. 206. Instead, Defendants looked outside of the Administrative Record and cited just two cases from 2012 in which the litigating parties wanted to retain their grandfathered health plans without covering contraceptive services. *See Roman Catholic Archdiocese of Atlanta v. Sebelius*, No. 1:12-CV-03489-WSD (N.D. Ga. 2014); *Diocese of Fort Wayne-S. Bend, Inc. v. Sebelius*, 988 F. Supp. 2d 958 (N.D. Ind. 2013). However, neither case shows that those entities sought to change their coverage in order to maintain their grandfathered status *in 2017* situations in which the administrative rule is a routine determination, insignificant in nature and impact, and inconsequential to the industry and to the public.'" *Utility Solid Waste Activities Grp. v. EPA*, 236 F.3d 749, 755 (D.C. Cir. 2001) (quoting *South Carolina v. Block*, 558 F. Supp. 1004, 1016 (D.S.C. 1983)). The significance of this litigation and the stakes involved, including hundreds of lawsuits, and several appeals to the Supreme Court, belies the Agencies' purported reliance on the "unnecessary," good cause exception for notice and comment.

The Agencies also assert that their provision for a post-issuance commentary period does away with the need for pre-issuance notice and comment. They solicited comments for 60 days following the issuance of the New IFRs. *See* 82 Fed. Reg. at 47792. None of the cases that Defendants cite support that position. Instead, each of them stand for the proposition that an agency may seek post-issuance commentary only if and only *after* having shown that it had good cause to avoid notice and comment rulemaking, a situation that is not present here.[10]

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[10] In *Petry v. Block*, 737 F.2d 1193 (D.C. Cir. 1984), the D.C. Circuit held that the Department of Agriculture had good cause to avoid notice and comment rulemaking before it held that remand to the agency for further proceedings was unnecessary in light of a post-promulgation comment period. In *Republic Steel Corp v. Costle*, 621 F.2d 797 (6th Cir. 1980), another case cited by Defendants, the court countenanced post-promulgation comments *after* finding good cause for avoiding notice-and-comment. Prior to *Petry,* the D.C. Circuit has held that "[p]ermitting submission of views after the effective date is no substitute for the right of interested persons to make their views known to the agency." *State of N.J., Dep't of Envtl. Prot. v. U.S. Envtl. Prot. Agency*, 626 F.2d 1038, 1049 (D.C. Cir. 1980). *Petry* did not alter this rule

There are several reasons why post-issuance comments do not comply with the notice and comment provisions of the APA. First, there is nothing in the APA that provides for post-issuance commentary. Second, participants are less likely to influence agency action in later stages of the agency decision-making process. This is especially the case where an agency has already issued interim rules which suggest that it has decided what federal policy should be. Post-issuance commentary does not ameliorate the need for notice and comment because by the time agencies issue interim rules, they are less likely to heed public input. *See United States v. Johnson*, 632 F.3d 912, 929 (5th Cir. 2011) ("[P]arties will have a greater opportunity for influencing agency decision making if they participate at an early stage."). Last, permitting post-issuance commentary *carte blanche* would write the notice and comment requirements out of the APA. *See id.*; *United States v. Gould,* 568 F.3d 459, 479 (4th Cir. 2009) ("[R]equesting post-promulgation comments makes a sham of the APA's rulemaking procedures."); *Paulsen v. Daniels*, 413 F.3d 999, 1005 (9th Cir. 2005) ("[I]t is antithetical to the structure and purpose of the APA for an agency to implement a rule first, and then seek comment later.").

Grasping at straws, Defendants argue that even if a single justification "standing alone" does not constitute good cause, the "combined effect" of several factors justified the Agencies' reliance on the good cause exception. An underlying assumption of this argument is that "[e]ach of the factors" provides at least some support for a finding that the Agencies had good cause to dispense with notice and comment. They do not. The three proffered factors to dispense with notice and comment offer no support. There was no deadline, much less an urgent one, to implement new rules. The New IFRs did not resolve any uncertainty and, as this case demonstrates, have not prevented ongoing litigation. And the blizzard of prior comments that the Agencies have received in past rounds of notice and comment rulemaking actually demonstrates that further comments are necessary given the public interest in this matter.

Certainly, an inquiry into whether an agency has "properly invoked 'good cause' proceeds case-by-case, sensitive to the totality of the factors at play." *Alcaraz v. Block*, 746 F.2d 593, 612 (9th Cir. 1984). And a court may consider the "combined effect" of multiple factors, which standing alone might not suffice to demonstrate "good cause." *See Nat'l Women, Infants, & Children Grocers Ass'n v. Food & Nutrition Serv.*, 416 F. Supp. 2d 92, 107 (D.D.C. 2006). But Defendants' arguments – even when viewed in their totality – provide no support for their proposition.[11]

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[11] Defendants' failure to follow the APA's notice and comment procedures was also not "harmless." "[T]he 'utter failure' to comply with notice and comment cannot be considered harmless if there is any uncertainty at all as to the effect of that failure." Reynolds, 710 F.3d at 11516. Rather, failure to abide by notice and comment rulemaking will only be found harmless in instances such as "when the administrative record demonstrates that the conclusion reached in the administrative rule was the only possible conclusion." *Id.* at 518. This is not the case here. In addition, the Defendant Agencies have never sought comments on whether publicly traded companies should be allowed to opt out of the Contraceptive Mandate for sincerely held religious reasons, whether a "moral exemption" should apply to the Mandate for all closely held corporations, or whether to exempt

For the above reasons, it is likely that the Commonwealth will succeed on its claim that the Defendants did not follow proper procedures in issuing the New IFRs.

**2. Substantive Provision**

Under the APA, an administrative rule has no legal effect if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Pursuant to this standard, it is likely that the Commonwealth will also succeed on its substantive challenge against the New IFRs because they contradict the text of the statute that they purport to interpret.

While an agency's interpretation of a statute is generally accorded great deference, an interpretation that conflicts with the statute's plain language is not. *See Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984). *Chevron* and its progeny dictate the appropriate framework for analyzing whether an agency's interpretation of a statute is permissible. First, a court must determine whether *Chevron* applies. *Chevron* deference is only appropriate in situations where Congress delegated rulemaking authority to a particular agency. *See Swallows Holding, Ltd. v. C.I.R.*, 515 F.3d 162, 168 (3d Cir. 2008). Next, "if the statutory language is clear and unambiguous, our inquiry ends and the plain meaning of the statute governs the action." *Id.* at 170. While review of an agency's interpretation under the "arbitrary and capricious" standard is decidedly narrow, an agency may not exercise its

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entities from additional notice requirements before opting out of providing contraceptive coverage for their employees.

authority in a manner "inconsistent with the administrative structure that Congress enacted into law." *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 126 (2000). Last, "[i]f the statute is ambiguous on the point, we defer at step two to the agency's interpretation so long as the construction is 'a reasonable policy choice for the agency to make.'" *National Cable & Telecommunications Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 986 (2005) (*quoting Chevron*, 467 U.S. at 845).

*i. Scope of HHS' Statutory Authority*

The takeaway is that *Chevron* deference does not extend to all agency action. In *United States v. Mead*, the Supreme Court explained that *Chevron* deference is only appropriate in situations where "Congress would expect the agency to be able to speak with the force of law." 553 U.S. 218, 229 (2001). Here, Congress delegated authority to the HRSA, a division of HHS, to interpret the scope of "preventive care" as defined by the ACA. The problem is that HHS, the Department of Labor, and the Department of Treasury have, through the New IFRs, interpreted the statute in a manner inconsistent with its text.

It bears mentioning, at this time, the remarkable breadth of the New IFRs. They are the proverbial exception that swallows the rule. The New IFRs permit various entities, on the basis of sincerely held religious beliefs or moral convictions, to opt out of providing contraceptive coverage – coverage that, under the text of the ACA as interpreted by the HRSA in August 2011, is supposedly mandatory. The Religious Exemption Rule allows all non-profit and for-profit entities, whether closely held or publicly traded, to deny contraceptive coverage based on sincerely held religious beliefs. The Moral Exemption Rule allows any non-profit or for-profit organization that is not publicly traded to deny contraceptive coverage for its employees for any sincerely held moral conviction. This means that boards of closely held corporations can vote, or their executives can decide, to deny contraceptive coverage for the corporation's women employees not just for religious reasons but also for any inchoate – albeit sincerely held – moral reason they can articulate. Who determines whether the expressed moral reason is sincere or not or, for that matter, whether it falls within the bounds of morality or is merely a preference choice, is not found within the terms of the Moral Exemption Rule. If one assumes that it is the Agency Defendants – or, indeed, any agency – then the Rule has conjured up a world where a government entity is empowered to impose its own version of morality on each one of us. That cannot be right. It "run[s] afoul of this country's vast history of legislative protections that single out and safeguard religious freedom but not moral philosophy." *Real Alternatives, Inc. v. Sec'y Dep't of Health & Human Servs.*, 867 F.3d 338, 350 (3d Cir. 2017) (emphasis added).

A simple hypothetical illustrates the insidious effect of the Moral Exemption Rule. It would allow an employer with a sincerely held moral conviction that women do not have a place in the workplace to simply stop providing contraceptive coverage. And, it may do so in an effort to impose its normative construct regarding a woman's place in the world on its workforce, confident that it would find solid support for that decision in the Moral Exemption Rule. It is difficult to comprehend a rule that does more to undermine the Contraceptive Mandate or that intrudes more into the lives of women.

*ii. The Text of the ACA*

Before analyzing whether the Agencies had authority to create the Moral and Religious Exemption Rules, a brief aside to RFRA is necessary. RFRA provides that government action cannot "substantially burden" the exercise of religion. It states that laws passed after 1993 are subject to RFRA "unless such law explicitly excludes such application. " 42 U.S.C. § 2000bb-3(b). The ACA was passed after 1993 and is thus subject to RFRA.[12] In *Hobby Lobby*, the Supreme Court held that the ACA does not explicitly exclude application of RFRA. *See Hobby Lobby*, 134 S. Ct. at 2775 n.30. It follows that any exception to the ACA required by RFRA is permissible. Bearing that in mind – and putting the issue of RFRA's application to the New IFRs on ice for now – the Court turns whether there is any language in the text of the ACA itself that would authorize the Agencies to issue the New IFRs – and concludes that there is not.

Congress created only a single exemption from the ACA's statutory mandate to cover women's preventive care and that is for "grandfathered health plans." 42 U.S.C. § 18011(e). "When Congress

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[12] Congress enacted RFRA in 1993 in response to *Employment Div., Dep't of Human Resources of Ore. v. Smith*, 494 U.S. 872 (1990), which held that "the Constitution does not require judges to engage in a case-by-case assessment of the religious burdens imposed by facially constitutional laws." *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 424 (2000).

provides exceptions in a statute . . . [t]he proper inference . . . is that Congress considered the issue of exceptions and, in the end, limited the statute to the ones set forth." *United States v. Johnson*, 529 U.S. 53, 58 (2000). Given that there is no religious or moral exemption in the explicit text of the statute and there is one for grandfathered health plans, it cannot be assumed that Congress authorized the Agencies to create any additional exemptions.

The fact that the statute does not contain language specifically precluding the Agency Defendants from developing exemptions does not change this result. Even absent the maxim that the inclusion of an exemption in a statute must be interpreted to mean that Congress intended no additional exemptions, "[n]ot every silence is pregnant." *Burns v. United States*, 501 U.S. 129, 136 (1991). Here, the mandatory language "shall" – found in the ACA's requirement that covered health plans "shall cover . . . with respect to women, such additional preventive care" as provided for in the HRSA guidelines – indicates quite the opposite: no exemptions created by HHS are permissible (unless they are required by RFRA). "An inference drawn from congressional silence certainly cannot be credited when it is contrary to all other textual and contextual evidence of congressional intent." *Id.* That conclusion carries particular weight here, because, in 2012, Congress explicitly rejected an attempt to add to the ACA an exemption similar to the Moral and Religious Rules. *See* S. Amdt. 1520, 112th Cong. (2011-2012); *see also Brown & Williamson*, 529 U.S. at 147 (rejection of an agency's interpretation by Congress is a factor courts consider when determining the meaning of a statute).

Nevertheless, Defendants argue that the textual structure of the ACA permits HHS to proscribe the "manner or reach of the coverage." They compare two subsections of the ACA, both of which provide for no-cost preventive care and screenings. The first concerns children, the second, women. Defendants then focus on the language in each subsection which authorizes the agency to issue guidelines regarding that subsection.[13] The subsection concerning children refers to "preventive care and screenings provided for in the comprehensive guidelines" from the HRSA. 42 U.S.C. § 300gg-13(a)(3). In contrast, the subsection concerning women refers to "such additional preventive care and screenings . . . **as** provided for in the comprehensive guidelines" from the HRSA. 42 U.S.C. § 300gg-13(a)(4) (emphasis added). Defendants note that the word "as" precedes the words "provided for in the comprehensive guidelines" in the women's subsection, but not the children's subsection. Proceeding from the statutory maxim

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[13] The full text of the two subsections are as follows:

A group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for – [the following services] . . .

(3) with respect to infants, children, and adolescents, evidence-informed preventive care and screenings ***provided*** for in the comprehensive guidelines supported by the Health Resources and Services Administration;

(4) with respect to women, such additional preventive care and screenings not described in paragraph (1) ***as provided for*** in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of this paragraph.

42 U.S.C. § 300gg-13(a)(3)–(4) (emphasis added).

that statutes should be interpreted, if possible, to give each word operative effect, *see Walters v. Metropolitan Educ. Enter., Inc.*, 519 U.S. 202, 209 (1997), Defendants conclude that the inclusion of the word "as" in the women's subsection means that HRSA may determine not only the services covered by the ACA, but also the manner or reach of that coverage.

This extrapolation from the statutory inclusion of the word "as" must, pursuant to another principle of statutory interpretation, be analyzed by looking to the dictionary definition of the word. *See Bonkowski v. Oberg Indus., Inc.*, 787 F.3d 190, 200 (3d Cir. 2015). The term "as" in this context is "[u]sed to indicate that something happens during the time when something else is taking place." *As*, Oxford English Dictionary Online, June 2017. At the time Congress passed the ACA, the HRSA had already promulgated guidelines interpreting children's preventive care. The HRSA had not promulgated such guidelines for women's preventive care. Thus, the ACA requires coverage "provided for" in HRSA guidelines for children's care and "as provided for" in HRSA guidelines for women's care. Giving effect to the use of the word "as" leads to the conclusion that the "as" is used in anticipation of HRSA issuing such guidelines and not to the conclusion that the ACA implicitly provides the Agencies with the authority to create non- statutory exemptions.

In sum, the ACA contains no statutory language allowing the Agencies to create such sweeping exemptions to the requirements to cover "preventive services," which, as interpreted by those same agencies, include mandatory no-cost coverage of contraceptive services. Nor does any rule of statutory construction warrant these exemptions.

*iii. Religious Freedom and Restoration Act*

The Agency Defendants also argue that they were compelled by RFRA to create the Religious Exemption Rule. It should be noted at the outset that they specifically do not propound this argument with respect to the Moral Exemption Rule. Thus, since the text of the statute is clear that non-statutory exemptions are not permitted, and Defendants admit that RFRA provides no support for it, the Moral Exemption Rule is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" under the APA. 5 U.S.C. § 706(2)(A). As set forth below, upon consideration of Defendants' argument regarding RFRA, the Court reaches the same conclusion with respect to the Religious Exemption Rule.

a. RFRA Does Not Support the Agencies' Interpretation

Turning now – finally – to the RFRA issue. One of the reasons the Agencies gave for issuing the New IFRs is that the Accommodation Process imposes a substantial burden on the exercise of religion. The Accommodation Process, as discussed earlier, allows religious objectors to notify their healthcare administrator of their religious objection, and the administrator would then have to provide the legally required contraceptive services directly to women covered under the employer's plan. The Agencies' stated belief that the Accommodation Process now imposes a substantial burden on the exercise of religion led them to create the broader exemptions set forth in the New IFRs. *See* 82 Fed. Reg. 47800. But their view that the Accommodation Process imposes a substantial burden on the exercise of religion has been specifically rejected by the Third Circuit, which found exactly to the contrary in *Geneva Coll. v. Sec'y U.S. Dep't of Health & Human Servs.*, 778 F.3d 422, 442 (3d Cir. 2015), *vacated and remanded on other grounds sub nom. Zubik v. Burwell*, 136 S. Ct. 1557 (2016).[14] There, the Third Circuit decisively and clearly held that the Accommodation Process does **not** impose a "substantial burden" under RFRA. And, in *Real Alternatives*, it reaffirmed that the Accommodation Process does not impose a substantial burden on religious exercise. *See* 867 F.3d at 356 n.18 ("[W]e continue to believe . . . that the regulation at issue . . . . did not impose a substantial burden."). Therefore, the Agency Defendants' interpretation of RFRA – that issuance of the Religious Exemption Rule is proper because the "substantial burden" that the Accommodation Process places on a person's exercise of religion – is erroneous as a matter of law. *See Williams v. Meltzler*, 132 F.3d 937, 946 (3d Cir. 1997) (on questions of law, administrative judgment is subject to plenary judicial review).[15]

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[14] While *Zubik* subsequently vacated *Geneva College,* it did so on other grounds. The Supreme Court expressly stated that "the Court does not decide whether petitioners' religious exercise has been substantially burdened . . . " *Zubik*, 136 S. Ct. at 1561.

[15] Although the Agencies asserted in the New IFRs that "[t]he Departments believe that agencies charged with administering a statute or associated regulations or guidance that imposes a substantial burden on the exercise of religion under RFRA have discretion in determining how to avoid the imposition of such

Defendants make much of having issued exemptions under prior regulations. For example, the Original Religious Exemption allowed churches and their integrated auxiliaries to opt out of the Contraceptive Mandate. However, the Supreme Court has held that exemptions like the one for churches and their integrated auxiliaries are required under RFRA and the First Amendment's free exercise protections. *See Hobby Lobby*, 134 S. Ct. at 2794 & n.14 (citing cases requiring exemptions for certain religious organizations). In *Real Alternatives*, the Third Circuit confirmed that the Original Religious Exemption was plainly required by federal and constitutional law in holding that exemptions and accommodations "may be extended to houses of worship and religious denominations without applying to all nonprofit entities in order to 'alleviate significant governmental interference with the ability of religious organizations to define and carry out

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burden," 82 Fed. Reg. 47800, Defendants now suggest otherwise. Defendants concede that the Agencies' interpretations of RFRA are not entitled to deference under RFRA. *See* Tr. 45 ("We are not arguing that the Agencies are entitled to *Chevron* deference writ large."). In any event, the Agencies' opinion is foreclosed by *Snoqualmie Indian Tribe v. F.E.R.C.*, 545 F.3d 1207 (9th Cir. 2008), in which the Ninth Circuit held that an agency's interpretation of RFRA is not accorded deference. They do argue that deference is appropriate for the Agencies' opinion that the Contraceptive Mandate does not serve a compelling interest as applied to religious objectors. However, this is beside the point because this question only becomes relevant if a court finds, first, that a government action imposes a substantial burden on the exercise of religion. As noted, the Accommodation Process does not impose a substantial burden on the exercise of religion so the Court need not conduct the compelling state interest analysis.

their religious missions.'" 867 F.3d at 352 (quoting *Corp. of Presiding Bishop of Church of Jesus Christ of Latter-day Saints v. Amos*, 483 U.S. 327 (1987). In contrast, the New IFRs are not required under RFRA because the Third Circuit – twice now – has foreclosed the Agencies' legal conclusion that the Accommodation Process imposes a substantial burden.

For these reasons, the Commonwealth has shown a likelihood of success on the merits of its APA claim that the New IFRs are arbitrary, capricious, and contrary to established law.

**b. Irreparable Harm**

As explained earlier, the second factor to consider in deciding the Commonwealth's motion is whether it has demonstrated that it is likely to suffer irreparable harm in the absence of a preliminary injunction. "Issuing a preliminary injunction based only on a possibility of irreparable harm is inconsistent with the characterization of injunctive relief as 'an extraordinary remedy' that may be awarded only upon a clear showing that the plaintiff is entitled to such relief." *Winter*, 555 U.S. at 21& 22 ("Our frequently reiterated standard requires plaintiffs seeking preliminary relief to demonstrate that irreparable injury is *likely* in the absence of an injunction.").

The Commonwealth asserts that it will suffer two harms in the absence of an injunction: First, significant damage to the Commonwealth's fiscal integrity; and second, harm to the health, safety, and wellness of the Commonwealth's female residents.

The Commonwealth offered the testimony of Doctors Carol Weisman, Samantha Butts, and Cynthia Chuang, as well as several declarations and exhibits to support its allegation of irreparable harm. From this testimony and from other evidence and affidavits in the record, the Court finds that it is likely that the New IFRs will result in direct and irreparable harm to the Commonwealth's fiscal integrity: The Commonwealth will become obligated to shoulder much of the burden of providing contraceptive services to those women who lose it because their health plans will opt out of coverage. *See* Steinberg Decl. ¶¶ 27-29; Medelsohn Decl. ¶ 15. Such women will seek contraceptive services elsewhere and, as Defendants noted in issuing the New IFRs, may turn to "multiple Federal, State, and local programs that provide free or subsidized contraceptives for low-income women" as alternative coverage. *See* 82 Fed. Reg. 47813, 47850. These programs in the Commonwealth include Medicaid, called "Medical Assistance," which relies on funding from both the State and federal governments; Family Planning Services Program; and the Commonwealth's network of clinics funded under the Title X grant program. *See* Allen Decl. ¶¶ 3-18; Steinberg Decl. [16]. Indeed, Dr. Chuang testified that she counsels patients without coverage for contraceptive services to seek coverage from Medicaid. Tr. 177-78. As women in Pennsylvania lose contraceptive coverage through their health insurance plans and turn to State programs, it is likely that the Commonwealth will bear the added financial burden occasioned by the increase in women who need contraceptive care coverage. See Decl. of Seth A. Mendelsohn ¶ 15; Allen Decl. ¶ 23.

Of course, "loss of money" is generally insufficient to merit a preliminary injunction because "monetary damages . . . are capable of ascertainment and award at final judgment " *Instant Air Freight Co. v. C.F. Air Freight, Inc.*, 882 F.2d 797, 801 (3d Cir. 1989). Here, however, the Commonwealth will not be able to recover any economic damages traceable to the implementation of the New IFRs. This is because a party – including the Commonwealth – may not seek monetary damages from the federal government. *See* 5 U.S.C. § 702 (providing that the federal government is immune from a suit for money damages). Therefore, if the New IFRs are ultimately struck down, the Commonwealth will be unable to recoup the money it expends on contraceptive care in the interim. In such circumstances, a preliminary injunction is appropriate. *See, e.g., N.J. Retail Merchants*, 669 F.3d at 388 (holding that a preliminary injunction is appropriate where a movant could not recover damages from a State due to sovereign immunity).

The Commonwealth's harm is not merely speculative; it is actual and imminent. *See Adams v. Freedom Forge Corp.*, 204 F.3d 475, 488 (3d Cir. 2000). The New IFRs estimate that *at least* 31,700 women will lose contraceptive coverage under the New Rules – and, as Plaintiff and amici persuasively argue, there are reasons to believe the number is significantly higher. *See* 82 Fed. Reg. 47,821. Thus, the only serious disagreement is not whether the Commonwealth will be harmed, but *how much* the Commonwealth will be harmed. Though Defendants argue that the Commonwealth has not identified any individual who has lost coverage already, there is no need to wait for the axe to fall before an injunction is appropriate, particularly where Defendants have estimated that it is about to fall on tens of thousands of women.[16] And the financial burden is impending. The Commonwealth anticipates that on January 1, 2018, when open enrollment begins for health plans regulated by ERISA, some health plans will remove no- cost contraceptive services pursuant to the New IFRs, and it is likely that Pennsylvanian women will seek contraceptive services through services funded by the State fisc.

While the legal harm to the integrity of the State fisc is important to obtain a preliminary injunction, of parallel importance is the significant harm to the Commonwealth's interest in protecting the health, safety, and well-being of its citizens. *See In re Oxycontin Antitrust Litig.*, 821 F. Supp. 2d 591, 601 (S.D.N.Y. 2011) (citing *Alfred L. Snapp*, 458 U.S. at 601-02). The potential harm faced by Pennsylvanian women and across the nation is enormous and irreversible. As employers take advantage of the New IFRs, access to no-cost contraceptive services for many women will be severely curtailed.

The Commonwealth's concern is that absent available cost-effective contraception, women will either forego contraception entirely or choose cheaper but less effective methods – individual choices which will result in an increase in unintended pregnancies. That, in turn, will inflict economic harm on the Commonwealth because unintended pregnancies are more likely to impose additional costs on

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[16] Since the New IFRs eliminate requirements to notify HHS of any decision to opt out, it is nearly impossible to know whether employers have already availed themselves of the New IFRs.

Pennsylvania's State-funded health programs. *See* Steinberg Decl., ¶ 30 (discussing study finding that 68% of unplanned births are paid for by public insurance programs, compared to only 38% of planned births).

The record evidence in support of this position is compelling. Contraceptives are, without question, effective at preventing unintended pregnancies. *See* Institute Report at 106. Eighty five percent of women who do not use any form of contraceptive services and who do not want to become pregnant, become pregnant in one year. *See id.* Those women who do use contraception are far less likely to have an unplanned pregnancy. *Id.* But, even for those who do use contraception, there is some chance of an unplanned pregnancy higher or lower depending upon the chosen contraceptive method. For example, a pamphlet issued by the Centers for Disease Control entitled "Effectiveness of Family Planning Methods" shows there are 6 to 12 pregnancies per 100 women who are on the contraceptive pill in any given year. *See* Exh. 17. Yet, for those who have an Intrauterine Device ("IUD") implanted there is less than one pregnancy per 100 women per year. *Id.* Thus, it is clear that an IUD is more effective than the pill at preventing unintended pregnancy. A reasonable conclusion from that is women, all else being equal, would make the contraceptive choice of an IUD rather than the pill. But, three doctors testified that an IUD can be cost-prohibitive for many women because it has higher upfront costs than the contraceptive pill. Tr. 90; 132-33; 176-78. Dr. Butts testified that, prior to the implementation of the ACA's Contraceptive Mandate, it was common for her patients not to have prescribed IUDs implanted, but since the Contraceptive Mandate, use of IUDs has increased dramatically. Tr. 132; 153. She testified that after the Mandate went into effect, making no-cost contraception services available to all women, the number of her patients who declined an IUD dropped significantly. *Id.* Meanwhile, she recorded a five-fold increase in the number of IUDs she inserted in the course of her medical practice. Tr. 153.

Dr. Chuang and Dr. Weisman also testified about a study ("MyNewOptions Study") they and others conducted between 2014 and 2016 of more than 900 Pennsylvanian women who were actively avoiding pregnancy. Reviewing insurance claims data, they found that the number of women using IUDs and other implants – contraceptive methods that carry the highest up-front costs but are the most effective – doubled in two years after the Contraceptive Mandate took effect. Tr. 178-87. Meanwhile, the number of women who did not use contraceptive services decreased by roughly 50% in the two years following the Mandate's effect.[17] *Id.* Doctors Chuang, Weisman, and Butts all attributed these changes to

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[17] Defendants cited a study from the Guttmacher Institute which found no changes in contraceptive use patterns among sexually active women. *See* Bearak, J.M. and Jones, R.K., "Did Contraceptive Use Patterns Change after the Affordable Care Act? A descriptive analysis," 27 *Women's Health Issues* 316 (Guttmacher Inst. May-June 2017). Unlike the MyNewOptions Study presented by Plaintiff, the Guttmacher study used survey data, which is less reliable than the claims data used in the MyNewOptions study. And, unlike the MyNewOptions study, the Guttmacher study did not focus on Pennsylvania where the rate of unintended pregnancy is significantly greater than the national average, and which is the focus of the preliminary injunction.

the effect of the Contraceptive Mandate, Tr. 90; 134; 187, and concluded that with the reduction in no-cost contraceptive insurance that will result from employer utilization of the New IFRs, more women will lose no- cost contraceptive coverage and the cost of their contraceptive services, to them, will rise. *See* Tr. 94. Thus, women will likely forgo contraceptive services or seek out less expensive and less effective types of contraceptive services in the absence of no-cost insurance coverage. *See id.;* Weisman Decl. ¶ 47; Chuang Decl. ¶¶ 36-39. Indeed, women cite cost as a significant factor in determining whether to purchase contraceptive services and which contraceptive services to use. *See* Adam Sonfield, *What is at Stake with the Federal Contraceptive Coverage Guarantee?* 20 Guttmacher Policy Review 8, 9 (2017).

The real life consequences, as amici point out, are significant: roughly 41% of unintended pregnancies in America are caused by inconsistent use of contraceptives.[18] These problems are particularly

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[18] The Contraceptive Mandate also affects women's health in other contexts as well. The Institute's Report, which recommended no-cost contraceptive coverage under the ACA, explained that contraceptive services are used to treat menstrual disorders, acne, hirsutism, and pelvic pain, in addition to assisting family planning and birth spacing. *See* Institute Report at 107. Contraceptive services are essential for women who face high-risk pregnancies or those for whom pregnancy may lead to significant complications. Even a short period of interrupted coverage will lead to irreparable harm because, as the Institute Report notes, women face severe complications, including death, from high-risk pregnancy. Dr. Butts also testified that decreased access to contraceptives will "increase pain and suffering for women who have [disorders such as pelvic pain and other medical conditions] . . . and to the extent that some of those unintended pregnancies are in women

acute in Pennsylvania, where the rate of unintended pregnancy is 53%, significantly higher than the national average. Tr. 152. The negative effects of even a short period of decreased access to no-cost contraceptive services are irreversible.

**c. Balance of the Equities**

The third factor that the Commonwealth must show is that the balance of the equities tips in favor of granting a preliminary injunction. "Balancing the equities" is jurisprudential "jargon for choosing between conflicting public interests." *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 609 (1943) (Frankfurter, J., concurring). Here, Congress has already struck the balance: Its passage of the Women's Health Amendment was to bridge the significant gender gap in healthcare costs between men and women. Senator Feinstein explained that "[w]omen of childbearing age spend 68 percent more in out-of-pocket health care costs than men." 155 Cong. Rec. 29302. And part of this problem stems from unintended pregnancies – an issue faced only by women. Senator Durbin explained that the purpose of the Women's Health Amendment was to "expand health insurance coverage to the vast majority of [the 17 million women of reproductive age in the United States who are uninsured and] . . . reduce unintended pregnancies." *Id.* at 26768. Where, as here, "Congress itself has struck the balance, has defined the weight to be given the competing interests, a court of equity is not justified in ignoring that pronouncement under

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with very serious medical disorders for whom pregnancy may be contraindicated [it] can increase risks in a life-threatening way." Tr. 140.

the guise of exercising equitable discretion." *Youngstown Sheet*, 343 U.S. at 609-10.

Here, given the Commonwealth's clear interest in securing the health and well-being of its women residents and containing its costs for contraceptive services, the balance of the equities heavily weighs in its favor. Defendants' assertion that there is "inherent harm to an agency in preventing it from implementing regulations that Congress found to be in the public interest to direct that agency to develop" does not change that balance. Defendants will not be prejudiced by a preliminary injunction. If the New IFRs were issued in violation of applicable law, they will have suffered no harm. If Defendants ultimately prevail, then a preliminary injunction will have merely delayed their preferred regulatory outcome.

**d. Public Interest**

When considering the public interest, a court is limited to evaluating "how such interest and conveniences are affected by the selection of an injunction over other enforcement mechanisms." *United States v. Oakland Cannabis Buyers' Co-op.*, 532 U.S. 483, 498 (2001). Here, a preliminary injunction is unquestionably in the public interest because it maintains the status quo pending the outcome of a trial on the merits. The New IFRs permit any entity to opt out of coverage within 30 to 60 days' notice to plan members. A trial on the merits will not conclude in that short span. A preliminary injunction will maintain the status quo: those with exemptions or accommodations prior to October 6, 2017 will maintain their status, those with injunctions preventing enforcement of the Contraceptive Mandate will maintain their injunctions, but those with coverage will maintain their coverage as well.

**IV. Conclusion**

Plaintiff, the Commonwealth of Pennsylvania, has demonstrated that it has met all four factors necessary to obtain a preliminary injunction. In this case, the Commonwealth is likely to succeed on the merits of its two APA claims; the Commonwealth is likely to suffer serious and irreparable harm in the absence of a preliminary injunction; the balance of the equities tips in favor of granting an injunction, and the public interest favors granting it as well. After weighing these four factors, as stated above, the Court concludes that a preliminary injunction is warranted. The Commonwealth's Motion for Preliminary Injunction will be granted and Defendants shall be enjoined from enforcing the New IFRs.

An appropriate order follows.

BY THE COURT:

/s/Wendy Beetlestone, J.
WENDY BEETLESTONE, J.

December 15, 2017

## APPENDIX E

## IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

| | |
|---|---|
| COMMONWEALTH OF PENNSYLVANIA,<br>Plaintiff,<br>v.<br>DONALD J. TRUMP, DONALD J. WRIGHT, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, STEVEN T. MNUCHIN, DEPARTMENT OF THE TREASURY, RENE ALEXANDER ACOSTA AND THE UNITED STATES DEPARTMENT OF LABOR,<br>Defendants. | CIVIL ACTION<br>NO. 17-4540 |

**ORDER**

**AND NOW**, this 15th day of December, 2017, upon consideration of the Commonwealth of Pennsylvania's Motion for a Preliminary Injunction (ECF No. 9), Defendants' Response thereto (ECF No. 15), Plaintiff's Reply in Support thereof (ECF No. 30), the Administrative Record (ECF Nos. 23 & 47), Briefs of the Amici Curiae (ECF Nos. 34, 35 & 36), and following a Hearing on Plaintiff's Motion on December 14, 2017, **IT IS HEREBY ORDERED** that the Motion is **GRANTED**.

It is **FURTHER ORDERED** that Defendants Eric D. Hargan, as Acting Secretary of the United States Department of Health and Human Services (substituted pursuant to Rule 25(d) of the Federal Rules of Civil Procedure); the United States Department of Health and Human Services; Steven T. Mnuchin, as Secretary of the United States Department of Treasury; the United States Department of Treasury, Rene Alexander Acosta, as Secretary of the United States Department of Labor; and the United States Department of Labor;[1] and their officers, agents, servants, employees, attorneys, designees, and subordinates, as well as any person acting in concert or participation with them, are hereby **ENJOINED** from enforcing the following Interim Final Rules pending further order of this Court:

1. Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act described at 82 Fed. Reg. 47792; and

2. Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act described at 82 Fed. Reg. 47838.

The Court has considered the issue of security pursuant to Rule 65(c) of the Federal Rules of Civil Procedure and determines that Defendants will not suffer any financial loss that warrants the need for

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[1] In light of the constitutional concerns associated with enjoining the President of the United States for a claim under the Administrative Procedure Act, this injunction does not apply to the President. *See Franklin v. Massachusetts*, 505 U.S. 788, 801 (1992).

the Plaintiff to post security. After considering the facts and circumstances of this case, the Court finds that security is unnecessary and exercises its discretion not to require the posting of security in this situation.

BY THE COURT:

/s/Wendy Beetlestone, J.
WENDY BEETLESTONE, J.

**APPENDIX F**

**IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

<table>
<tr><td>COMMONWEALTH OF PENNSYLVANIA AND STATE OF NEW JERSEY,<br><br>Plaintiffs,<br><br>v.<br><br>DONALD J. TRUMP, PRESIDENT OF THE UNITED STATES, ALEX M. AZAR II, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, STEVEN T. MNUCHIN, UNITED STATES DEPARTMENT OF THE TREASURY, PATRICK PIZZELLA, THE UNITED STATES DEPARTMENT OF LABOR, AND THE UNITED STATES OF AMERICA,<br><br>Defendants,<br><br>LITTLE SISTERS OF THE POOR SAINTS PETER AND PAUL HOME,<br><br>Defendant-Intervenor.</td><td>CIVIL ACTION<br><br>NO. 17-4540<br><br>FILED<br>JUL 30, 2019<br>Kate Barkman,<br>Clerk</td></tr>
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**ORDER**

**AND NOW**, this 30th day of July, 2019,

**WHEREAS** on October 6, 2017, Defendants promulgated two Interim Final Rules, referred to as the Religious Exemption IFR, *see Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act*, 82 Fed. Reg. 47,792 (Oct. 13, 2017), and the Moral Exemption IFR, *see Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act*, 82 Fed. Reg. 47,838 (Oct. 13, 2017) ("Moral Exemption IFR") (collectively, "the IFRs");

**WHEREAS** on October, 11, 2017, the Commonwealth of Pennsylvania initiated this suit seeking to enjoin enforcement of the IFRs, arguing the IFRs: (1) failed to comply with the notice-and-comment procedures required by the Administrative Procedure Act ("APA"), 5 U.S.C. § 551, *et seq.*; (2) were "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" in violation of the substantive provisions of the APA, 5 U.S.C. § 706(2)(A); (3) violated Title VII of the Civil Rights Act, 42 U.S.C. § 2000e-2, *et seq.*; (4) violated the Equal Protection Guarantee of the Fifth Amendment, U.S. Const. amend. V; and, (5) violated the Establishment Clause, U.S. Const. amend. I;

**WHEREAS** on December 15, 2017, this Court granted the motion for a preliminary injunction, finding the Commonwealth was likely to succeed on its claims that the IFRs violated both the procedural and substantive strictures of the APA; it did not, however, reach the merits of the other statutory or constitutional claims, *see Pennsylvania v. Trump*, 281 F. Supp.3d 553 (E.D. Pa. 2017) (hereinafter "*Trump I*");

**WHEREAS** on November 15, 2018, while their appeal of the preliminary injunction was pending before the Third Circuit, the Agencies promulgated two new rules that "finalize[ d]" the IFRs, *see Religious Exemptions and Accommodations/or Coverage o/Certain Preventive Services Under the Affordable Care Act*, 83 Fed. Reg. 57,536 (Nov. 15, 2018) ("Final Religious Exemption"); *Moral Exemptions and Accommodations/or Coverage of Certain Preventive Services Under the Affordable Care Act*, 83 Fed. Reg. 57,592 (Nov. 15, 2018) ("Final Moral Exemption") (collectively "the Final Rules");

**WHEREAS** on December 14, 2019, the Commonwealth-now joined by New Jersey (collectively "the States")—filed an Amended Complaint and a Second Motion for a Preliminary Injunction, seeking to enjoin enforcement of the Final Rules, arguing the Final Rules: (1) failed to comply with the notice-and-comment procedures required by the APA; (2) were "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" in violation of the substantive provisions of the APA; (3) violated Title VII of the Civil Rights Act; (4) violated the Equal Protection Guarantee of the Fifth Amendment; and, (5) violated the Establishment Clause;

**WHEREAS** on January 14, 2019, this Court granted the second motion for a nationwide preliminary injunction, finding the States were likely to succeed on their claims that the Final Rules violated both the procedural and substantive strictures of the APA; again, however, the Court did not reach the merits of the other statutory or constitutional claims, *see Pennsylvania v. Trump*, 351 F. Supp.3d 791 (E.D. Pa. 2017) (hereinafter "*Trump II*");

**WHEREAS** on March 28, 2019, Defendants filed a Motion to Dismiss the Amended Complaint (ECF No. 157), and, on March 29, 2019, Defendant-Intervenor filed a Motion to Dismiss the Amended Complaint (ECF No. 159);

**WHEREAS** on May 15, 2019, the States filed a Motion for Summary Judgment (ECF No. 170), asking the Court to vacate the Final Rules on the grounds that they: (1) failed to comply with the notice-and-comment procedures required by the APA; (2) were "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" in violation of the substantive provisions of the APA; (3) violated Title VII of the Civil Rights Act; (4) violated the Equal Protection Guarantee of the Fifth Amendment; and, (5) violated the Establishment Clause;

**WHEREAS** on June 14, 2019, Defendants and Defendant-Intervenor filed cross-motions for summary judgment (ECF Nos. 205 & 206);

**WHEREAS** on July 12, 2019, the Third Circuit issued an opinion affirming the nationwide injunction issued by the Court in *Trump II* on the grounds that the States were likely to succeed on their claims that the Final Rules violated both the procedural and substantive requirements of the APA, *see Pennsylvania v. President United States*, 2019 WL 3057657 (3d Cir. July 12, 2019) (hereinafter "*Trump III*");

**WHEREAS** on July 23, 2019, the Court held a conference call with the parties regarding case management in light of the Third Circuit's decision in

*Trump Ill*, during which Defendants and Defendant-Intervenor represented that they intend to seek further appellate review of the Third Circuit's decision;

**WHEREAS** on July 25, 2019, the parties submitted letters to the Court regarding case management, in which:

- Defendants sought entry of final judgment as to the procedural and substantive APA claims pursuant to Fed. R. Civ. P. 54, and dismissal of the remaining statutory and constitutional claims as moot; or, in the alternative a stay of further proceedings (ECF No. 230);
- The States sought resolution of all outstanding statutory and constitutional claims, as well as alternative arguments made in support of the procedural and substantive APA claims, which were not explicitly addressed in *Trump II* or *Trump III* (ECF No. 231);

**WHEREAS** enforcement of the Final Rules has been enjoined nationwide for violations of the procedural and substantive requirements of the APA, rendering it unnecessary to reach the States' alternative claims and arguments at this juncture;

**WHEREAS** further appellate review may impact the posture and resolution of the outstanding claims and issues raised by the parties in the pending motions to dismiss and motions for summary judgment, making resolution of those motions at present an inefficient use of judicial resources, *see Dietz v. Bouldin*, 136 S. Ct. 1885, 1892 (2016) ("[D]istrict courts have the inherent authority to manage their dockets and courtrooms with a view toward the efficient and expedient resolution of cases."); *see also Smith v. Manasquan Bank*, 2018 WL 2958664, at *1 (D.N.J. June 13, 2018) ("The power to stay a proceeding pending appeal is derived from the inherent power of a court to efficiently manage its own docket.");

**IT IS HEREBY ORDERED** that further proceedings in this matter are **STAYED**, and the parties' pending motions to dismiss and motions for summary judgment (ECF Nos. 157, 159, 205, 206) are **HELD IN ABEYANCE**, pending resolution of any appeal of the Third Circuit's decision in *Trump III* by Defendants and Defendant-Intervenor. The stay does not affect the nationwide injunction issued in *Trump II*, and affirmed in *Trump III*, which remains in effect.

**IT IS FURTHER ORDERED** that the parties shall submit a joint status report to the Court on **OCTOBER 25, 2019**, and every **NINETY DAYS** thereafter.

BY THE COURT:
/s/ Wendy Beetlestone
WENDY BEETLESTONE, J.

ENT'D JUL 31 2019

# APPENDIX G

## RELEVANT STATUTORY PROVISIONS

42 U.S.C. § 2000bb-1 provides:

**§ 2000bb-1. Free exercise of religion protected**

(a) In general

Government shall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability, except as provided in subsection (b) of this section.

(b) Exception

Government may substantially burden a person's exercise of religion only if it demonstrates that application of the burden to the person—

(1) is in furtherance of a compelling governmental interest; and

(2) is the least restrictive means of furthering that compelling governmental interest.

(c) Judicial relief

A person whose religious exercise has been burdened in violation of this section may assert that violation as a claim or defense in a judicial proceeding and obtain appropriate relief against a government. Standing to assert a claim or defense under this section shall be governed by the general rules of standing under article III of the Constitution.

42 U.S.C. § 300gg-13(a)(4) provides:

**§ 300gg-13. Coverage of preventive health services**

(a) In general

A group health plan and a health insurances issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for—

* * *

(4) with respect to women, such additional preventive care and screenings not described in paragraph (1) as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of this paragraph.

* * *

29 U.S.C. § 1185d provides:

**§ 1185d. Additional market reforms**

(a) General rule

Except as provided in subsection (b)—

(1) the provisions of part A of title XXVII of the Public Health Service Act (as amended by the Patient Protection and Affordable Care Act) shall apply to group health plans, and health insurance issuers providing health insurance coverage in connection with group health plans, as if included in this subpart; and

(2) to the extent that any provision of this part conflicts with a provision of such part A with respect to group health plans, or health insurance issuers providing health insurance coverage in connection with group health plans, the provisions of such part A shall apply.

(b) Exception

Notwithstanding subsection (a), the provisions of sections 2716 and 2718 of title XXVII of the Public Health Service Act (as amended by the Patient Protection and Affordable Care Act) shall not apply with respect to self-insured group health plans, and the provisions of this part shall continue to apply to such plans as if such sections of the Public Health Service Act (as so amended) had not been enacted.

26 U.S.C. § 4980D provides:

**§ 4980D. Failure to meet certain group health plan requirements**

(a) General rule.—There is hereby imposed a tax on any failure of a group health plan to meet the requirements of chapter 100 (relating to group health plan requirements).

(b) Amount of tax.—

(1) In general.—The amount of the tax imposed by subsection (a) on any failure shall be $100 for each day in the noncompliance period with respect to each individual to whom such failure relates.

(2) Noncompliance period.—For purposes of this section, the term "noncompliance period" means, with respect to any failure, the period—

(A) beginning on the date such failure first occurs, and

(B) ending on the date such failure is corrected.

(3) Minimum tax for noncompliance period where failure discovered after notice of examination.—Notwithstanding paragraphs (1) and (2) of subsection (c)—

(A) In general.—In the case of 1 or more failures with respect to an individual—

(i) which are not corrected before the date a notice of examination of income tax liability is sent to the employer, and

(ii) which occurred or continued during the period under examination, the amount of tax imposed by subsection (a) by reason of such failures with respect to such individual shall not be less than the lesser of

$2,500 or the amount of tax which would be imposed by subsection (a) without regard to such paragraphs.

(B) Higher minimum tax where violations are more than de minimis.—To the extent violations for which any person is liable under subsection (e) for any year are more than de minimis, subparagraph (A) shall be applied by substituting "$15,000" for "$2,500" with respect to such person.

(C) Exception for church plans.—This paragraph shall not apply to any failure under a church plan (as defined in section 414(e)).

(c) Limitations on amount of tax.—

(1) Tax not to apply where failure not discovered exercising reasonable diligence.—No tax shall be imposed by subsection (a) on any failure during any period for which it is established to the satisfaction of the Secretary that the person otherwise liable for such tax did not know, and exercising reasonable diligence would not have known, that such failure existed.

(2) Tax not to apply to failures corrected within certain periods.—No tax shall be imposed by subsection (a) on any failure if—

(A) such failure was due to reasonable cause and not to willful neglect, and

(B) (i) in the case of a plan other than a church plan (as defined in section 414(e)), such failure is corrected during the 30-day period beginning on the first date the person otherwise liable for such tax knew, or exercising reasonable diligence would have known, that such failure existed, and

(ii) in the case of a church plan (as so defined), such failure is corrected before the close of the correction period (determined under the rules of section 414(e)(4)(C)).

(3) Overall limitation for unintentional failures.— In the case of failures which are due to reasonable cause and not to willful neglect—

(A) Single employer plans.—

(i) In general.—In the case of failures with respect to plans other than specified multiple employer health plans, the tax imposed by subsection (a) for failures during the taxable year of the employer shall not exceed the amount equal to the lesser of—

(I) 10 percent of the aggregate amount paid or incurred by the employer (or predecessor employer) during the preceding taxable year for group health plans, or

(II) $500,000.

(ii) Taxable years in the case of certain controlled groups.—For purposes of this subparagraph, if not all persons who are treated as a single employer for purposes of this section have the same taxable year, the taxable years taken into account shall be determined under principles similar to the principles of section 1561.

(B) Specified multiple employer health plans.—

(i) In general.—In the case of failures with respect to a specified multiple employer health plan, the tax imposed by subsection (a) for failures during the taxable year of the trust forming part of such plan shall not exceed the amount equal to the lesser of—

(I) 10 percent of the amount paid or incurred by such trust during such taxable year to provide medical care (as defined in section 9832(d)(3)) directly or through insurance, reimbursement, or otherwise, or

(II) $500,000.

For purposes of the preceding sentence, all plans of which the same trust forms a part shall be treated as one plan.

(ii) Special rule for employers required to pay tax.—If an employer is assessed a tax imposed by subsection (a) by reason of a failure with respect to a specified multiple employer health plan, the limit shall be determined under subparagraph (A) (and not under this subparagraph) and as if such plan were not a specified multiple employer health plan.

(4) Waiver by Secretary.—In the case of a failure which is due to reasonable cause and not to willful neglect, the Secretary may waive part or all of the tax imposed by subsection (a) to the extent that the payment of such tax would be excessive relative to the failure involved.

(d) Tax not to apply to certain insured small employer plans.—

(1) In general.—In the case of a group health plan of a small employer which provides health insurance coverage solely through a contract with a health insurance issuer, no tax shall be imposed by this section on the employer on any failure (other than a failure attributable to section 9811) which is solely because of the health insurance coverage offered by such issuer.

(2) Small employer.—

(A) In general.—For purposes of paragraph (1), the term "small employer" means, with respect to a calendar year and a plan year, an employer who employed an average of at least 2 but not more than 50 employees on business days during the preceding calendar year and who employs at least 2 employees on the first day of the plan year. For purposes of the preceding sentence, all persons treated as a single employer under subsection (b), (c), (m), or (o) of section 414 shall be treated as one employer.

(B) Employers not in existence in preceding year.—In the case of an employer which was not in existence throughout the preceding calendar year, the determination of whether such employer is a small employer shall be based on the average number of employees that it is reasonably expected such employer will employ on business days in the current calendar year.

(C) Predecessors.—Any reference in this paragraph to an employer shall include a reference to any predecessor of such employer.

(3) Health insurance coverage; health insurance issuer.—For purposes of paragraph (1), the terms "health insurance coverage" and "health insurance issuer" have the respective meanings given such terms by section 9832.

(e) Liability for tax.—The following shall be liable for the tax imposed by subsection (a) on a failure:

(1) Except as otherwise provided in this subsection, the employer.

(2) In the case of a multiemployer plan, the plan.

(3) In the case of a failure under section 9803 (relating to guaranteed renewability) with respect to a plan described in subsection (f)(2)(B), the plan.

(f) Definitions.—For purposes of this section—

(1) Group health plan.—The term "group health plan" has the meaning given such term by section 9832(a).

(2) Specified multiple employer health plan.—The term "specified multiple employer health plan" means a group health plan which is—

(A) any multiemployer plan, or

(B) any multiple employer welfare arrangement (as defined in section 3(40) of the Employee Retirement Income Security Act of 1974, as in effect on the date of the enactment of this section).

(3) Correction.—A failure of a group health plan shall be treated as corrected if—

(A) such failure is retroactively undone to the extent possible, and

(B) the person to whom the failure relates is placed in a financial position which is as good as such person would have been in had such failure not occurred.

26 U.S.C. § 4980H provides:

**§ 4980H. Shared responsibility for employers regarding health coverage.**

(a) Large employers not offering health coverage

If—

(1) any applicable large employer fails to offer to its full-time employees (and their dependents) the opportunity to enroll in minimum essential coverage under an eligible employer-sponsored plan (as defined in section 5000A(f)(2)) for any month, and

(2) at least one full-time employee of the applicable large employer has been certified to the employer under section 1411 of the Patient Protection and Affordable Care Act as having enrolled for such month in a qualified health plan with respect to which an applicable premium tax credit or cost-sharing reduction is allowed or paid with respect to the employee, then there is hereby imposed on the employer an assessable payment equal to the product of the applicable payment amount and the number of individuals employed by the employer as full-time employees during such month.

(b) Large employers offering coverage with employees who qualify for premium tax credits or cost-sharing reductions

(1) In general

If—

(A) an applicable large employer offers to its full-time employees (and their dependents) the opportunity to enroll in minimum essential coverage under an eligible employer-sponsored plan (as defined in section 5000A(f)(2)) for any month, and

(B) 1 or more full-time employees of the applicable large employer has been certified to the employer under section 1411 of the Patient Protection and Affordable Care Act as having enrolled for such month in a qualified health plan with respect to which an applicable premium tax credit or cost-sharing reduction is allowed or paid with respect to the employee, then there is hereby imposed on the employer an assessable payment equal to the product of the number of full-time employees of the applicable large employer described in subparagraph (B) for such month and an amount equal to 1/12 of $3,000.

(2) Overall limitation

The aggregate amount of tax determined under paragraph (1) with respect to all employees of an applicable large employer for any month shall not exceed the product of the applicable payment amount and the number of individuals employed by the employer as full-time employees during such month.

(c) Definitions and special rules

For purposes of this section—

(1) Applicable payment amount.

The term “applicable payment amount” means, with respect to any month, 1/12 of $2,000.

(2) Applicable large employer

(A) In general

The term “applicable large employer” means, with respect to a calendar year, an employer who employed an average of at least 50 full-time employees on business days during the preceding calendar year.

(B) Exemption for certain employers

(i) In general.

An employer shall not be considered to employ more than 50 full-time employees if—

(I) the employer's workforce exceeds 50 full-time employees for 120 days or fewer during the calendar year, and

(II) the employees in excess of 50 employed during such 120-day period were seasonal workers.

(ii) Definition of seasonal workers

The term "seasonal worker" means a worker who performs labor or services on a seasonal basis as defined by the Secretary of Labor, including workers covered by section 500.20(s)(1) of title 29, Code of Federal Regulations and retail workers employed exclusively during holiday seasons.

(C) Rules for determining employer size

For purposes of this paragraph—

(i) Application of aggregation rule for employers

All persons treated as a single employer under subsection (b), (c), (m), or (o) of section 414 of the Internal Revenue Code of 1986 shall be treated as 1 employer.

(ii) Employers not in existence in preceding year

In the case of an employer which was not in existence throughout the preceding calendar year, the determination of whether such employer is an applicable large employer shall be based on the average number of employees that it is reasonably expected such employer will employ on business days in the current calendar year.

(iii) Predecessors

Any reference in this subsection to an employer shall include a reference to any predecessor of such employer.

(D) Application of employer size to assessable penalties

(i) In general

The number of individuals employed by an applicable large employer as full- time employees during any month shall be reduced by 30 solely for purposes of calculating—

(I) the assessable payment under subsection (a), or

(II) the overall limitation under subsection (b)(2).

(ii) Aggregation

In the case of persons treated as 1 employer under subparagraph (C)(i), only 1 reduction under subclause (I) or (II) shall be allowed with respect to such persons and such reduction shall be allocated among such persons ratably on the basis of the number of full-time employees employed by each such person.

(E) Full-time equivalents treated as full-time employees

Solely for purposes of determining whether an employer is an applicable large employer under this paragraph, an employer shall, in addition to the number of full-time employees for any month otherwise determined, include for such month a number of full-time employees determined by dividing the aggregate number of hours of service of employees who are not full-time employees for the month by 120.

(F) Exemption for health coverage under TRICARE or the Department of Veterans Affairs.—-Solely for purposes of determining whether an employer is an applicable large employer under this paragraph for any month, an individual shall not be taken into account as an employee for such month if such individual has medical coverage for such month under—

(i) chapter 55 of title 10, United States Code, including coverage under the TRICARE program, or

(ii) under a health care program under chapter 17 or 18 of title 38, United States Code, as determined by the Secretary of Veterans Affairs, in coordination with the Secretary of Health and Human Services and the Secretary.

(3) Applicable premium tax credit and cost-sharing reduction.

The term "applicable premium tax credit and cost-sharing reduction" means—

(A) any premium tax credit allowed under section 36B,

(B) any cost-sharing reduction under section 1402 of the Patient Protection and Affordable Care Act, and

(C) any advance payment of such credit or reduction under section 1412 of such Act.

(4) Full-time employee

(A) In general

The term “full-time employee” means, with respect to any month, an employee who is employed on average at least 30 hours of service per week.

(B) Hours of service

The Secretary, in consultation with the Secretary of Labor, shall prescribe such regulations, rules, and guidance as may be necessary to determine the hours of service of an employee, including rules for the application of this paragraph to employees who are not compensated on an hourly basis.

(5) Inflation adjustment

(A) In general

In the case of any calendar year after 2014, each of the dollar amounts in subsection (b) and paragraph (1) shall be increased by an amount equal to the product of—

(i) such dollar amount, and

(ii) the premium adjustment percentage (as defined in section 1302(c)(4) of the Patient Protection and Affordable Care Act) for the calendar year.

(B) Rounding

If the amount of any increase under subparagraph (A) is not a multiple of \$10, such increase shall be rounded to the next lowest multiple of \$10.

(6) Other definitions

Any term used in this section which is also used in the Patient Protection and Affordable Care Act shall have the same meaning as when used in such Act.

(7) Tax nondeductible

For denial of deduction for the tax imposed by this section, see section 275(a)(6).

(d) Administration and procedure

(1) In general

Any assessable payment provided by this section shall be paid upon notice and demand by the Secretary, and shall be assessed and collected in the same manner as an assessable penalty under subchapter B of chapter 68.

(2) Time for payment

The Secretary may provide for the payment of any assessable payment provided by this section on an annual, monthly, or other periodic basis as the Secretary may prescribe.

(3) Coordination with credits, etc.

The Secretary shall prescribe rules, regulations, or guidance for the repayment of any assessable payment (including interest) if such payment is based on the allowance or payment of an applicable premium tax credit or cost- sharing reduction with respect to an employee, such allowance or payment is subsequently disallowed, and the assessable payment would not have been required to be made but for such allowance or payment.

26 U.S.C. § 5000A provides:

**§ 5000A. Requirement to maintain minimum essential coverage**

(a) Requirement to maintain minimum essential coverage

An applicable individual shall for each month beginning after 2013 ensure that the individual, and any dependent of the individual who is an applicable individual, is covered under minimum essential coverage for such month.

(b) Shared responsibility payment

(1) In general

If a taxpayer who is an applicable individual, or an applicable individual for whom the taxpayer is liable under paragraph (3), fails to meet the requirement of subsection (a) for 1 or more months, then, except as provided in subsection (e), there is hereby imposed on the taxpayer a penalty with respect to such failures in the amount determined under subsection (c).

(2) Inclusion with return

Any penalty imposed by this section with respect to any month shall be included with a taxpayer's return under chapter 1 for the taxable year which includes such month.

(3) Payment of penalty

If an individual with respect to whom a penalty is imposed by this section for any month—

(A) is a dependent (as defined in section 152) of another taxpayer for the other taxpayer's taxable year including such month, such other taxpayer shall be liable for such penalty, or

(B) files a joint return for the taxable year including such month, such individual and the spouse of such individual shall be jointly liable for such penalty.

(c) Amount of penalty

(1) In general

The amount of the penalty imposed by this section on any taxpayer for any taxable year with respect to failures described in subsection (b)(1) shall be equal to the lesser of—

(A) the sum of the monthly penalty amounts determined under paragraph (2) for months in the taxable year during which 1 or more such failures occurred, or

(B) an amount equal to the national average premium for qualified health plans which have a bronze level of coverage, provide coverage for the applicable family size involved, and are offered through Exchanges for plan years beginning in the calendar year with or within which the taxable year ends.

(2) Monthly penalty amounts

For purposes of paragraph (1)(A), the monthly penalty amount with respect to any taxpayer for any month during which any failure described in subsection (b)(1) occurred is an amount equal to 1/12 of the greater of the following amounts:

(A) Flat dollar amount

An amount equal to the lesser of—

(i) the sum of the applicable dollar amounts for all individuals with respect to whom such failure occurred during such month, or

(ii) 300 percent of the applicable dollar amount (determined without regard to paragraph (3)(C)) for the calendar year with or within which the taxable year ends.

(B) Percentage of income

An amount equal to the following percentage of the excess of the taxpayer's household income for the taxable year over the amount of gross income specified in section 6012(a)(1) with respect to the taxpayer for the taxable year:

(i) 1.0 percent for taxable years beginning in 2014.

(ii) 2.0 percent for taxable years beginning in 2015.

(iii) Zero percent for taxable years beginning after 2015.

(3) Applicable dollar amount

For purposes of paragraph (1)—

(A) In general

Except as provided in subparagraphs (B) and (C), the applicable dollar amount is $0.

(B) Phase in

The applicable dollar amount is $95 for 2014 and $325 for 2015.

(C) Special rule for individuals under age 18

If an applicable individual has not attained the age of 18 as of the beginning of a month, the applicable dollar amount with respect to such individual for the month shall be equal to one-half of the applicable dollar amount for the calendar year in which the month occurs.

(4) Terms relating to income and families

For purposes of this section—

(A) Family size

The family size involved with respect to any taxpayer shall be equal to the number of individuals for whom the taxpayer is allowed a deduction under section 151 (relating to allowance of deduction for personal exemptions) for the taxable year.

(B) Household income

The term “household income” means, with respect to any taxpayer for any taxable year, an amount equal to the sum of—

(i) the modified adjusted gross income of the taxpayer, plus

(ii) the aggregate modified adjusted gross incomes of all other individuals who—

(I) were taken into account in determining the taxpayer’s family size under paragraph (1), and

(II) were required to file a return of tax imposed by section 1 for the taxable year.

(C) Modified adjusted gross income

The term “modified adjusted gross income” means adjusted gross income increased by—

(i) any amount excluded from gross income under section 911, and

(ii) any amount of interest received or accrued by the taxpayer during the taxable year which is exempt from tax.

(d) Applicable individual

For purposes of this section—

(1) In general

The term "applicable individual" means, with respect to any month, an individual other than an individual described in paragraph (2), (3), or (4).

(2) Religious exemptions

(A) Religious conscience exemptions

(i) In general

Such term shall not include any individual for any month if such individual has in effect an exemption under section 1311(d)(4)(H) of the Patient Protection and Affordable Care Act which certifies that—

(I) such individual is a member of a recognized religious sect or division thereof which is described in section 1402(g)(1), and is adherent of established tenets or teachings of such sect or division as described in such section; or

(II) such individual is a member of a religious sect or division thereof which is not described in section 1402(g)(1), who relies solely on a religious method of healing, and for whom the acceptance of medical health services would be inconsistent with the religious beliefs of the individual.

(ii) Special rules

(I) Medical health services defined

For purposes of this subparagraph, the term "medical health services" does not include routine dental, vision and hearing services, midwifery services, vaccinations, necessary medical services provided to children, services required by law or by a third party, and such other services as the Secretary of Health and Human Services may provide in implementing section 1311(d)(4)(H) of the Patient Protection and Affordable Care Act.

(II) Attestation required

Clause (i)(II) shall apply to an individual for months in a taxable year only if the information provided by the individual under section 1411(b)(5)(A) of such Act includes an attestation that the individual has not received medical health services during the preceding taxable year.

(B) Health care sharing ministry

(i) In general

Such term shall not include any individual for any month if such individual is a member of a health care sharing ministry for the month.

(ii) Health care sharing ministry

The term "health care sharing ministry" means an organization—

(I) which is described in section 501(c)(3) and is exempt from taxation under section 501(a),

(II) members of which share a common set of ethical or religious beliefs and share medical expenses among members in accordance with those beliefs and without regard to the State in which a member resides or is employed,

(III) members of which retain membership even after they develop a medical condition,

(IV) which (or a predecessor of which) has been in existence at all times since December 31, 1999, and medical expenses of its members have been shared continuously and without interruption since at least December 31, 1999, and

(V) which conducts an annual audit which is performed by an independent certified public accounting firm in accordance with generally accepted accounting principles and which is made available to the public upon request.

(3) Individuals not lawfully present

Such term shall not include an individual for any month if for the month the individual is not a citizen or national of the United States or an alien lawfully present in the United States.

(4) Incarcerated individuals

Such term shall not include an individual for any month if for the month the individual is incarcerated, other than incarceration pending the disposition of charges.

(e) Exemptions

No penalty shall be imposed under subsection (a) with respect to—

(1) Individuals who cannot afford coverage

(A) In general

Any applicable individual for any month if the applicable individual's required contribution (determined on an annual basis) for coverage for the month exceeds 8 percent of such individual's household income for the taxable year described in section 1412(b)(1)(B) of the Patient Protection and Affordable Care Act. For purposes of applying this subparagraph, the taxpayer's household income shall be increased by any exclusion from gross income for any portion of the required contribution made through a salary reduction arrangement.

(B) Required contribution

For purposes of this paragraph, the term "required contribution" means—

(i) in the case of an individual eligible to purchase minimum essential coverage consisting of coverage through an eligible-employer-sponsored plan, the portion of the annual premium which would be paid by the individual (without regard to whether paid through salary reduction or otherwise) for self-only coverage, or

(ii) in the case of an individual eligible only to purchase minimum essential coverage described in subsection (f)(1)(C), the annual premium for the lowest cost bronze plan available in the individual market through the Exchange in the State in the rating area in which the individual resides (without regard to whether the individual purchased a qualified health plan through the Exchange), reduced by the amount of the credit allowable under section 36B for the taxable year (determined as if the individual was covered by a qualified health plan offered through the Exchange for the entire taxable year).

(C) Special rules for individuals related to employees

For purposes of subparagraph (B)(i), if an applicable individual is eligible for minimum essential coverage through an employer by reason of a relationship to an employee, the determination under subparagraph (A) shall be made by reference to1 required contribution of the employee.

(D) Indexing

In the case of plan years beginning in any calendar year after 2014, subparagraph (A) shall be applied by substituting for "8 percent" the percentage the Secretary of Health and Human Services determines reflects the excess of the rate of premium growth between the preceding calendar year and 2013 over the rate of income growth for such period.

(2) Taxpayers with income below filing threshold

Any applicable individual for any month during a calendar year if the individual's household income for the taxable year described in section 1412(b)(1)(B) of the Patient Protection and Affordable Care Act is less than the amount of gross income specified in section 6012(a)(1) with respect to the taxpayer.

(3) Members of Indian tribes

Any applicable individual for any month during which the individual is a member of an Indian tribe (as defined in section 45A(c)(6)).

(4) Months during short coverage gaps

(A) In general

Any month the last day of which occurred during a period in which the applicable individual was not covered by minimum essential coverage for a continuous period of less than 3 months.

(B) Special rules

For purposes of applying this paragraph—

(i) the length of a continuous period shall be determined without regard to the calendar years in which months in such period occur,

(ii) if a continuous period is greater than the period allowed under subparagraph (A), no exception shall be provided under this paragraph for any month in the period, and

(iii) if there is more than 1 continuous period described in subparagraph (A) covering months in a calendar year, the exception provided by this paragraph shall only apply to months in the first of such periods.

The Secretary shall prescribe rules for the collection of the penalty imposed by this section in cases where continuous periods include months in more than 1 taxable year.

(5) Hardships

Any applicable individual who for any month is determined by the Secretary of Health and Human Services under section 1311(d)(4)(H) to have suffered a hardship with respect to the capability to obtain coverage under a qualified health plan.

(f) Minimum essential coverage

For purposes of this section—

(1) In general

The term "minimum essential coverage" means any of the following:

(A) Government sponsored programs

Coverage under—

(i) the Medicare program under part A of title XVIII of the Social Security Act,

(ii) the Medicaid program under title XIX of the Social Security Act,

(iii) the CHIP program under title XXI of the Social Security Act or under a qualified CHIP look-alike program (as defined in section 2107(g) of the Social Security Act),

(iv) medical coverage under chapter 55 of title 10, United States Code, including coverage under the TRICARE program;

(v) a health care program under chapter 17 or 18 of title 38, United States Code, as determined by the Secretary of Veterans Affairs, in coordination with the Secretary of Health and Human Services and the Secretary,

(vi) a health plan under section 2504(e) of title 22, United States Code (relating to Peace Corps volunteers);2 or

(vii) the Nonappropriated Fund Health Benefits Program of the Department of Defense, established under section 349 of the National Defense Authorization Act for Fiscal Year 1995 (Public Law 103-337; 10 U.S.C. 1587 note).

(B) Employer-sponsored plan

Coverage under an eligible employer-sponsored plan.

(C) Plans in the individual market

Coverage under a health plan offered in the individual market within a State.

(D) Grandfathered health plan

Coverage under a grandfathered health plan.

(E) Other coverage

Such other health benefits coverage, such as a State health benefits risk pool, as the Secretary of Health and Human Services, in coordination with the Secretary, recognizes for purposes of this subsection.

(2) Eligible employer-sponsored plan

The term "eligible employer-sponsored plan" means, with respect to any employee, a group health plan or group health insurance coverage offered by an employer to the employee which is—

(A) a governmental plan (within the meaning of section 2791(d)(8) of the Public Health Service Act), or

(B) any other plan or coverage offered in the small or large group market within a State.

Such term shall include a grandfathered health plan described in paragraph (1)(D) offered in a group market.

(3) Excepted benefits not treated as minimum essential coverage

The term "minimum essential coverage" shall not include health insurance coverage which consists of coverage of excepted benefits—

(A) described in paragraph (1) of subsection (c) of section 2791 of the Public Health Service Act; or

(B) described in paragraph (2), (3), or (4) of such subsection if the benefits are provided under a separate policy, certificate, or contract of insurance.

(4) Individuals residing outside United States or residents of territories

Any applicable individual shall be treated as having minimum essential coverage for any month—

(A) if such month occurs during any period described in subparagraph (A) or (B) of section 911(d)(1) which is applicable to the individual, or

(B) if such individual is a bona fide resident of any possession of the United States (as determined under section 937(a)) for such month.

(5) Insurance-related terms

Any term used in this section which is also used in title I of the Patient Protection and Affordable Care Act shall have the same meaning as when used in such title.

(g) Administration and procedure

(1) In general

The penalty provided by this section shall be paid upon notice and demand by the Secretary, and except as provided in paragraph (2), shall be assessed and collected in the same manner as an assessable penalty under subchapter B of chapter 68.

(2) Special rules

Notwithstanding any other provision of law—

(A) Waiver of criminal penalties

In the case of any failure by a taxpayer to timely pay any penalty imposed by this section, such taxpayer shall not be subject to any criminal prosecution or penalty with respect to such failure.

(B) Limitations on liens and levies

The Secretary shall not—

(i) file notice of lien with respect to any property of a taxpayer by reason of any failure to pay the penalty imposed by this section, or

(ii) levy on any such property with respect to such failure.

45 C.F.R. § 147.132 provides:

**§ 147.132. Religious exemptions in connection with coverage of certain preventive health services.**

(a) *Objecting entities*. (1) Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections specified below. Thus the Health Resources and Service Administration will exempt from any guidelines' requirements that relate to the provision of contraceptive services:

(i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent the non-governmental plan sponsor objects as specified in paragraph (a)(2) of this section. Such non-governmental plan sponsors include, but are not limited to, the following entities—

(A) A church, an integrated auxiliary of a church, a convention or association of churches, or a religious order.

(B) A nonprofit organization.

(C) A closely held for-profit entity.

(D) A for-profit entity that is not closely held.

(E) Any other non-governmental employer.

(ii) A group health plan, and health insurance coverage provided in connection with a group health plan, where the plan or coverage is established or maintained by a church, an integrated auxiliary of a church, a convention or association of churches, a religious order, a nonprofit organization, or other non-governmental organization or association, to the extent the plan sponsor responsible for establishing and/or maintaining the plan objects as specified in paragraph (a)(2) of this section. The exemption in this paragraph applies to each employer, organization, or plan sponsor that adopts the plan;

(iii) An institution of higher education as defined in 20 U.S.C. 1002, which is non-governmental, in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to "plan participants and beneficiaries" will be interpreted as references to student enrollees and their covered dependents; and

(iv) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under this subparagraph (iv), the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under

§ 147.130(a)(1)(iv) unless it is also exempt from that requirement.

(2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects, based on its sincerely held religious beliefs, to its establishing, maintaining, providing, offering, or arranging for (as applicable):

(i) Coverage or payments for some or all contraceptive services; or

(ii) A plan, issuer, or third party administrator that provides or arranges such coverage or payments.

(b) *Objecting individuals*. Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713 (a)(1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs. Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.

(c) *Definition*. For the purposes of this section, reference to "contraceptive" services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv).

(d) *Severability*. Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.